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Evoke Enters Exclusive Commercial Supply Agreement for Active Pharmaceutical Ingredient in EVK-001

SOLANA BEACH, Calif., May 19, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), today announced that it has signed an exclusive commercial supply agreement with COSMA S.p.A. for the active pharmaceutical ingredient (API) in its product candidate EVK-001. EVK-001 is the Company's novel nasal spray for delivery of metoclopramide for the symptomatic relief of acute and recurrent diabetic gastroparesis in women.

Pursuant to the agreement, COSMA will provide Evoke with the API for EVK-001 that will enable the production of commercial scale quantities in accordance with the FDA standards for chemistry, manufacturing, and controls (CMC). COSMA has been providing metoclopramide to Evoke for several years in association with its clinical trial material supply needs and registration batches, as well as commercial scale production. COSMA has been involved in chemistry and pharmaceuticals broadly for multiple other pharmaceutical firms since 1949. It has an integrated manufacturing facility which is FDA approved, and has the flexibility to widen its production capacity and to harmonize good manufacturing practice (GMP) requirements.

"With this agreement in place, we have finalized another step toward commercial production of EVK-001. COSMA has a wealth of experience providing pharmaceutical companies with quality products, and we have full confidence in their ability to meet the potential needs for the manufacture of EVK-001," Dave Gonyer, R.Ph., Evoke's President and CEO stated. "We continue to be active behind the scenes to ensure that EVK-001 is positioned to get to market as soon as possible, should the drug candidate receive FDA approval. We are excited about the potential market opportunity for our drug candidate and look forward to completing the clinical trial process and providing data early in the third quarter of this year."

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 <u>www.EvokePharma.com</u> 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 forwardlooking 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 timing of data from the Phase 3 clinical trial of EVK-001; the sufficiency of such data and the other activities completed to data providing a basis for regulatory approval of EVK-001 and the timing thereof; the potential commercialization of EVK-001; and COSMA's ability to meet Evoke's needs in connection with manufacturing the API for EVK-001 while complying with CMC and GMP requirements. 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 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, and Evoke cannot be certain that it will be able to obtain regulatory approval for 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; Evoke may not be able to successfully commercialize EVK-001, if approved, as a result of risks associated with market

acceptance, coverage and reimbursement and competing products; risks that issues with future manufacturing production will arise, whether as a result of noncompliance with CMC or GMP requirements or otherwise; Evoke's reliance on outsourcing arrangements for many of its activities, including clinical development, manufacturing and supply of EVK-001; 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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