

# Evoke Pharma Enters Commercialization Agreement with EVERSANA Life Sciences for Gimoti™

January 23, 2020

EVERSANA to commercialize and distribute Gimoti in the U.S.

EVERSANA to provide \$5 million revolving credit facility upon FDA approval

SOLANA BEACH, Calif. and CHICAGO, Jan. 23, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, and EVERSANA<sup>TM</sup>, an independent provider of global commercial services to the life science industry, today announced a collaboration to utilize EVERSANA's integrated suite of outsourced services to commercialize and distribute Gimoti<sup>TM</sup> irthe United States (U.S.).

Gimoti is Evoke's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis. The U.S. Food and Drug Administration (FDA) has set a target goal date under the Prescription Drug User Fee Act (PDUFA) of June 19, 2020. Subject to FDA approval, EVERSANA will fund and commercialize Gimoti and manage substantially all activities related to marketing, market access, distribution, sales team, patient reimbursement, and provide related support services.

"We are excited to partner with EVERSANA, which will allow us to efficiently and rapidly prepare to commercialize Gimoti without the need to invest in a large corporate infrastructure and build out of a sales force. Under the agreement, we will leverage EVERSANA's integrated suite of capabilities, including highly experienced personnel with proficiency in all key facets of pharmaceutical product commercialization," commented Dave Gonyer, President and CEO. "We will continue to work with FDA in their review of our NDA while simultaneously coordinating with EVERSANA for a potential product launch this year."

Jim Lang, CEO of EVERSANA added, "Innovative therapies like Gimoti allow innovative commercialization strategies. That's why we've built a comprehensive integrated commercial services platform, powered by more than 2,000 employees, to bring innovative products to the market, reducing cost and risk while simultaneously improving outcomes. We are very pleased to enter into a strategic partnership with Evoke and look forward to supporting all aspects of commercialization to ensure a smooth and successful launch of Gimoti."

Under the terms of the agreement, Evoke maintains ownership of the Gimoti New Drug Application (NDA) as well as all legal, regulatory, and manufacturing responsibilities. Evoke will record sales for Gimoti to EVERSANA's third party logistics division and retain more than 80% of product profits. EVERSANA will utilize its internal sales organization along with other commercial functions for market access, marketing, distribution and patient support services. EVERSANA will receive reimbursement of certain costs and a percentage of product profits in the mid to high teens when Gimoti net sales surpass certain administrative, manufacturing and commercialization costs. In addition, EVERSANA has agreed to provide up to \$5.0 million revolving credit facility to Evoke subject to NDA approval, and certain other conditions. Evoke and EVERSANA retain the right to terminate the agreement upon certain events, including any change of control of Evoke. The term of the agreement is five years following FDA approval, after which Evoke will recapture all product sales and corresponding commercialization responsibilities. Gimoti is under patent protection in the United States until 2030 and upon approval would be the only non-oral out-patient treatment for women suffering from diabetic gastroparesis in the United States.

In addition, Evoke and Novos Growth Partners have mutually agreed to terminate the commercialization agreement dated January 5, 2019.

## **About Gastroparesis**

Gastroparesis is a debilitating, episodic condition that disproportionately affects adult women and is characterized by slow or delayed gastric emptying of the stomach's contents after meals, often resulting in flares of symptoms that include nausea, vomiting, abdominal pain and bloating. Vomiting and gastric emptying delays can cause unpredictable absorption of food and oral medications, which complicate glucose control and can lead to dehydration and malnutrition. These clinical manifestations of gastroparesis also potentially render existing oral drug treatment options ineffective. If approved, Gimoti would be the first non-oral drug treatment for symptoms associated with acute and recurrent diabetic gastroparesis in adult women and would represent the first significant advancement in the treatment of gastroparesis in 40 years.

## 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 nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Metoclopramide is currently available only in oral and injectable formulations and is the only drug currently approved in the United States to treat gastroparesis. Visit <u>www.EvokePharma.com</u> for more information.

## About EVERSANA Life Science Services, LLC

EVERSANA<sup>TM</sup> is an independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient

experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science solutions for a healthier world. To learn more about EVERSANA, visit eversana.com or connect through LinkedIn and Twitter.

## 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 potential timing of FDA action on the NDA and potential approval and product launch for Gimoti; the expected length of patent protection for Gimoti; and the expected availability of the new revolving loan facility following approval of the Gimoti NDA, if any. 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 not be able to obtain, maintain and enforce its patents and other intellectual property rights, and the scope of patent protection may not provide the protections Evoke expects; the risk that the funding under the new \$5.0 million revolving credit facility may not be completed on the timeframe Evoke expects, or at all, including as a result of an event of default under the terms of the loan agreement; the potential for the FDA to delay the PDUFA target goal date due to the FDA's internal resource constraints or other reasons; Evoke may be unable to timely and successfully address the deficiencies raised in the Complete Response Letter (CRL) regarding Gimoti, including as a result of adverse findings from a root cause analysis or data from the newly manufactured product batches not fully addressing issues raised by the FDA in the CRL and type A meeting; FDA may not agree with Evoke's conclusion of the results from the manufacturing testing or the root cause analysis, or may require Evoke to conduct additional studies; the inherent risks of clinical development and regulatory approval of Gimoti; Evoke's dependence on third parties for the manufacture of Gimoti and analysis of the manufacturing data; Evoke is entirely dependent on the success of Gimoti; Evoke will require substantial additional funding to continue its operations into the second quarter of 2020, and may be unable to raise capital or obtain funds when needed, including to fund ongoing operations; Evoke could face significant additional costs due to litigation or other events; 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.

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

EVERSANA Contact: Sarah Zwicky Tel: 414-434-4691 sarah.zwicky@eversana.com



Source: Evoke Pharma, Inc.