Evoke Pharma Signs Commercial and Financial Agreement for its Lead Product Gimoti™ in the U.S. with Novos Growth Partners

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Novos to provide fully integrated commercial function for Evoke and non-dilutive financing for the commercialization of Gimoti, extending cash runway into 2020

Evoke will retain greater than 80% of product profits following approval

SOLANA BEACH, Calif., Jan. 07, 2019 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced a partnership with Novos Growth Partners (NGP) to commercialize Gimoti™, the Company's nasal spray product candidate for the relief of symptoms in adult women with acute and recurrent diabetic gastroparesis. NGP will manage the commercial operations for a dedicated sales team to market Gimoti to gastroenterologists and other targeted health care providers, if approved. NGP will also provide non-dilutive working capital for commercialization costs prior to and following product launch. The U.S. Food and Drug Administration (FDA) has set a target goal date under the Pharmaceutical Drug User Fee Act (PDUFA) of April 1, 2019.

"This is a landmark agreement for Evoke and leverages NGP's fully integrated commercialization platform and experienced management team for the commercialization of Gimoti. The combination of NGP's commercial capabilities and financial resources address several of our corporate interests while allowing us to retain product ownership, a significant percentage of sales revenue and additional strategic flexibilities. We are working closely with NGP in preparation for Gimoti's potential product launch this year," commented Dave Gonyer, President and CEO.

Under the terms of the agreement, Evoke maintains ownership of the Gimoti New Drug Application (NDA). In addition, Evoke will maintain legal, regulatory, and manufacturing responsibilities. Evoke will also retain a contract sales organization, which would be managed by NGP and who will finance the working capital for launch. Evoke will record sales for Gimoti and retain more than 80% of product profits. NGP will receive a percentage of product profits in the mid to high teens as a service fee once Gimoti net sales surpass commercialization costs. In addition to the non-dilutive working capital, NGP has agreed to provide up to $5.0 million to Evoke in a line of credit following NDA approval. Evoke and NGP 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, after which Evoke will recapture 100% of product sales and corresponding responsibilities.

As of December 31, 2018, Evoke had approximately $5.3 million in cash. Evoke believes this cash, the NGP working capital to cover commercialization costs and the NGP credit line, extend its cash runway into 2020 without considering any future Gimoti product revenue.

Gimoti is expected to be launched in the United States during 2019, if approved by the FDA. Gimoti is under patent protection in the United States until 2030 and would be the only non-oral out-patient treatment for women suffering from diabetic gastroparesis in the United States. Gastroparesis is a condition that affects the normal spontaneous movement of the muscles in the stomach and can cause the stomach to slow down or stop completely. It is most often associated with diabetes. Gimoti allows patients to nasally deliver effective drug therapy while bypassing the stomach, which in patients with gastroparesis, oral treatments can be unpredictably absorbed. Today, patients receive millions of prescriptions each year for oral medications to treat this debilitating disease.

Stifel, Nicolaus & Company, Incorporated acted as exclusive financial advisor to Evoke in this transaction.

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 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 potential timing of FDA action on the NDA and potential approval and product launch for Gimoti; NGP’s use of its commercialization platform and team for the commercialization of Gimoti; Evoke’s retention of a contract sales organization; NGP providing a working capital loan and line of credit and Evoke’s projected cash runway; Evoke’s expectations on future Gimoti product sales; and expected duration of patent protection 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: the potential for FDA to delay the PDUFA target action date due to FDA’s internal resource constraints or other reasons; FDA may disagree that the existing safety database and efficacy data is sufficient to allow approval of the NDA, including as a result of the potential review issues identified by FDA in the Day-74 Letter such as, among others, C_{max} falling below the bioequivalence range in the comparative exposure PK trial, the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration, the adequacy of the proposed REMS included in the NDA, and the existing data supporting a female-only indication; FDA may not agree with Evoke’s interpretation of the results of clinical trials of Gimoti; later developments with FDA that may be inconsistent with the already completed pre-NDA meetings; the possibility of an advisory committee meeting related to the NDA; the inherent risks of clinical development of Gimoti; Evoke’s reliance on a third party, NGP, for critical aspects of the commercialization of Gimoti; the performance of NGP and its adherence to the terms of the agreement with Evoke; Evoke’s ability to timely secure a contract sale organization; Evoke could face unexpected costs due to additional regulatory requests, litigation or other events; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will approve the NDA for Gimoti or that Evoke and NGP will successfully commercialize Gimoti; Evoke may require substantial additional funding, and may be unable to raise capital or obtain funds under the working capital loan or line of credit when needed, including to fund ongoing operations; 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; 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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