

Evoke Pharma Inc
Form 8-K
January 04, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 4, 2017

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

505 Lomas Santa Fe Drive, Suite 270

001-36075
(Commission

File Number)

20-8447886
(IRS Employer

Identification No.)

92075

Solana Beach, California
(Address of Principal Executive Offices) **(Zip Code)**
Registrant's telephone number, including area code: (858) 345-1494

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On January 4, 2017, Evoke Pharma, Inc. (the Company) a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, provided additional data from the Phase 3 trial of Gimoti, its nasal delivery of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. Although the Phase 3 trial failed to reach its primary endpoint, data also demonstrated that patients with moderate to severe symptoms, which included 105 of the 205 patients (51%) enrolled in the study, responded statistically significantly better when treated with Gimoti than those treated with placebo at multiple time points in the Intent-to-Treat (ITT) and Per Protocol populations (Table 1). There were also clinically and statistically significant improvements in nausea and abdominal pain, which are two of the more severe and debilitating symptoms of gastroparesis (Table 2).

These results in patients with moderate to severe symptoms are consistent with the U.S. Food and Drug Administration (FDA) guidance on the clinical evaluation of drugs for the treatment of gastroparesis issued in July 2015 (*Gastroparesis: Clinical Evaluation of Drugs for Treatment, Draft Guidance*). This guidance represents the FDA's current thinking on the evaluation of treatments for gastroparesis and states that trials should enroll patients with higher symptom severity in order to optimize the ability to demonstrate a treatment effect. At the time this guidance was issued, the Company's Phase 3 study, designed to include patients with a range of symptom severity, had been actively enrolling for more than a year. The overall efficacy results were not significant, due in large part to the milder patients who responded to placebo. Importantly, the efficacy of Gimoti was demonstrated in the subset of patients described in the guidance, i.e., those who entered the study with higher symptom severity.

Phase 3 safety data revealed no significant adverse effects and were consistent with favorable results from previous Gimoti studies. In particular, there were no adverse events of special interest, such as the central nervous system (CNS) effects observed with oral and parenteral metoclopramide (Table 3). There have been no reports of tardive dyskinesia among the 1,311 exposed healthy volunteers and patients over the clinical development program.

The trial was a U.S. multicenter, randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of Gimoti compared to placebo in adult female subjects with symptomatic diabetic gastroparesis and delayed gastric emptying. Eligible patients were randomized 1:1 between Gimoti or placebo administered as a single nasal spray four times daily; 30 minutes before meals and at bedtime for a total of four weeks. The primary endpoint was the change in the total symptom score from baseline to week four and was not statistically significant in the ITT group (N=205, p = 0.881). Safety and additional efficacy results are summarized in the tables below.

Table 1: Phase 3 Estimated Mean Change from Baseline in Mean Daily GSA Total Scores: Moderate to Severe Study Populations

	Time			
Population	Period	Placebo ¹	Gimoti ¹	p-value ²
Intent-to-Treat	Week 1	(N = 53)	(N = 52)	0.036
	Week 2	-0.387	-0.588	0.025
	Week 3	-0.614	-0.950	0.039
	Week 4	-0.749	-1.096	0.085*

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		-0.856	-1.220	
		(N = 40)	(N = 38)	
Per Protocol	Week 1	-0.362	-0.623	0.019
	Week 2	-0.625	-1.040	0.015
	Week 3	-0.714	-1.286	0.003
	Week 4	-0.841	-1.373	0.014

Table 2: Mean Change from Baseline in Mean Daily Nausea and Upper Abdominal Pain Score in Intent-to-Treat Population with Moderate to Severe Symptoms

Symptom	Time	Placebo ¹	Gimoti ¹	<i>p</i> -value ²
	Period	(N = 53)	(N = 52)	
Nausea	Week 1	-0.370	-0.859	0.001
	Week 2	-0.696	-1.149	0.032*
	Week 3	-0.818	-1.242	0.043
	Week 4	-0.905	-1.404	0.027
Upper Abdominal Pain	Week 1	-0.394	-0.641	0.025
	Week 2	-0.554	-0.990	0.016
	Week 3	-0.690	-1.194	0.008
	Week 4	-0.791	-1.218	0.047

¹ LSMeans from ANCOVA

² *p*-value is obtained from an ANCOVA model with fixed effect for treatment group and the baseline value as a covariate. If the normality assumption was not met, the *p*-value was obtained from a rank ANCOVA test and denoted with an *.

Table 3: Selected Treatment-Emergent Adverse Events Reported by More than 2 Subjects in Any Treatment Group

Adverse Event	Placebo	Gimoti
	(N = 103)	(N = 102)
Headache	7 (7%)	5 (5%)
Nasal discomfort	4 (4%)	1 (1%)
Epistaxis	2 (2%)	1 (1%)
Fatigue	1 (1%)	2 (2%)

Forward-Looking Statements.

The Company cautions you that statements included in this Current Report on Form 8-K 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, contemplate, 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 for Gimoti to have a positive impact on the lives of the patients who use it. The inclusion of forward-looking statements should not be regarded as a representation by the Company 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 the Company's business, including, without limitation: the data reported only includes a portion of the patients in the Phase 3 clinical trial of Gimoti and that the Phase 3 trial failed to reach its primary endpoint; risks associated with successfully commencing and receiving favorable results from the planned pharmacokinetic trial; later developments with the FDA that may be inconsistent with the already completed pre-new drug application (NDA) meetings, including that the FDA will not accept selected data from our Phase 3 clinical trial; the FDA may change its recommendations regarding

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evaluation of drugs for the treatment of gastroparesis; the inherent risks of clinical development of Gimoti; the Company is entirely dependent on the success of Gimoti, and the Company cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; risks associated with manufacturing new formulations of Gimoti for use in the pharmacokinetic (PK) trial; the Company's dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; the Company may require additional funding to complete the PK trial and submit the NDA, and will require substantial additional funding to

commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; the Company may not be able to successfully commercialize Gimoti, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; and other risks detailed in the periodic reports the Company 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 the Company 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EVOKE PHARMA, INC.

Date: January 4, 2017

By: /s/ Matthew J. D Onofrio

Name: Matthew J. D Onofrio

Title: Executive Vice President,

Chief Business Officer and Secretary