



Evoke Pharma Reports Third Quarter 2020 Financial Results

November 10, 2020

Gimoti™ commercial launch underway

SOLANA BEACH, Calif., Nov. 10, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced its financial results for the third quarter ended September 30, 2020 and recent corporate developments.

"The third quarter was marked by preparation for the commercial launch of GIMOTI, which we successfully implemented in early fourth quarter. The launch of GIMOTI to treat symptoms of acute and recurrent diabetic gastroparesis with our commercial partner EVERSANA marked a pivotal event for the Company," said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. "As a nasally delivered product, GIMOTI has distinct differences over oral formulations of metoclopramide. It is the only outpatient non-oral treatment option to help improve the quality of life for patients suffering with diabetic gastroparesis. Initial prescriptions of GIMOTI have already been filled at the EVERSANA specialty pharmacy through our patient support team at EvokeAssist™. We believe this vital support program will aid both physicians and patients through enrollment, reimbursement, and delivery of GIMOTI directly to the patient. Given the milestones achieved for commercial preparedness, we believe we are in a strong position as we launch GIMOTI and address a significant unmet medical need for millions of patients suffering from diabetic gastroparesis."

Third Quarter 2020 Developments and Recent Progress:

- Launched GIMOTI with commercial partner, EVERSANA, in line with prior guidance
- Implemented EvokeAssist, an integrated patient support program
- Appointed Chris Quesenberry as Chief Commercial Officer for GIMOTI through our Commercial partner, EVERSANA
- Built an entire commercial team, including field sales and call center
- Completed manufacturing of the first commercial lot of GIMOTI

Third Quarter 2020 Financial Review

For the third quarter of 2020, net loss was approximately \$2.1 million, or \$0.08 per share, compared to a net loss of approximately \$1.6 million, or \$0.07 per share, for the third quarter of 2019.

Research and development expenses totaled approximately \$0.2 million for the third quarter of 2020, compared to approximately \$0.8 million for the third quarter of 2019. The decrease during the three months ended September 30, 2020 was primarily due to the decrease in research and development activity following the GIMOTI NDA approval in June 2020.

For the third quarter of 2020, general and administrative expenses were approximately \$1.9 million compared to approximately \$0.8 million for the third quarter of 2019. The increase during the three months ended September 30, 2020 was primarily due to increased costs associated with our commercialization and selling activities. Of the costs incurred during the third quarter of 2020, approximately \$745,000 were related to commercialization activities.

Total operating expenses for the third quarter of 2020 were approximately \$2.1 million, compared to total operating expenses of approximately \$1.6 million for the third quarter of 2019.

As of September 30, 2020, the Company's cash and cash equivalents were approximately \$6.3 million. The Company expects that its current cash balance will be sufficient to support operations into the second quarter of 2021, without consideration of potential future GIMOTI revenue.

About Evoke Pharma, Inc.

Evoke is a specialty pharmaceutical company focused primarily on the commercialization and development of drugs to treat GI disorders and diseases. The Company developed GIMOTI, a nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adults. GIMOTI is available by prescription through the EvokeAssist™ patient support center. Visit www.GimotiRx.com for more information.

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 GI symptoms as well as other systemic complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. GIMOTI is absorbed in the nasal cavity and bypasses the erratic gastric absorption often seen in gastroparesis patients. Prior to FDA approval to commercially market GIMOTI, metoclopramide was only available in oral and injectable formulations. It remains the only drug currently approved in the United States to treat gastroparesis. Visit www.EvokePharma.com for more information.

About Gimoti™ (metoclopramide) nasal spray

GIMOTI is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Important Safety Information

WARNING: TARDIVE DYSKINESIA

- Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage.
- Discontinue GIMOTI in patients who develop signs or symptoms of TD. In some patients, symptoms may lessen or resolve after metoclopramide is stopped.
- Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the increased risk of developing TD with longer-term use.

GIMOTI is not recommended for use in:

- Pediatric patients due to the risk of developing tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates.
- Moderate or severe hepatic impairment (ChildPugh B or C), moderate or severe renal impairment (creatinine clearance less than 60 mL/minute), and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions.

GIMOTI is contraindicated:

- In patients with a history of tardive dyskinesia (TD) or a dystonic reaction to metoclopramide.
- When stimulation of gastrointestinal motility might be dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation).
- In patients with pheochromocytoma or other catecholamine-releasing paragangliomas. Metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to release of catecholamines from the tumor.
- In patients with epilepsy. Metoclopramide may increase the frequency and severity of seizures.
- In patients with hypersensitivity to metoclopramide. Reactions have included laryngeal and glossal angioedema and bronchospasm.

Potential adverse reactions associated with metoclopramide include: Tardive dyskinesia (TD), other extrapyramidal effects (EPS), parkinsonism symptoms, motor restlessness, neuroleptic malignant syndrome (NMS), depression, suicidal ideation and suicide, hypertension, fluid retention, hyperprolactinemia, effects on the ability to drive and operate machinery.

Most common adverse reactions (≥5%) for GIMOTI are: dysgeusia, headache, and fatigue.

These are not all of the possible side effects of GIMOTI. Call your doctor for medical advice about whether you should take GIMOTI and the possible risk factors and side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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 size of the gastroparesis market and the potential of GIMOTI to provide an important new alternative to current treatment options. 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's and EVERSANA's ability to successfully drive market demand for GIMOTI; Evoke's ability to obtain additional financing as needed to support its operations, including through the EVERSANA line of credit which is subject to certain customary conditions; the COVID-19 pandemic may disrupt Evoke's and EVERSANA's business operations impairing the ability to commercialize GIMOTI and Evoke's ability to generate any product revenue; Evoke's dependence on third parties for the manufacture of GIMOTI; Evoke is entirely dependent on the success of GIMOTI; inadequate efficacy or unexpected adverse side effects relating to GIMOTI that could result in recalls or product liability claims; Evoke's ability to obtain and maintain intellectual property protection for GIMOTI; 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.

TABLES TO FOLLOW

Evoke Pharm, Inc.

Balance Sheets

September

December

	<u>30, 2020</u>	<u>31, 2019</u>
	<u>(Unaudited)</u>	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,280,656	\$ 5,663,833
Prepaid expenses	336,432	581,706
Inventory	86,145	—
Other current assets	11,551	—
Total current assets	<u>6,714,784</u>	<u>6,245,539</u>
Operating lease right-of-use asset	36,115	138,538
Other assets	—	11,551
Total assets	<u>\$ 6,750,899</u>	<u>\$ 6,395,628</u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 765,603	\$ 1,033,383
Accrued compensation	715,423	843,162
Operating lease liability	36,115	138,538
Paycheck protection program loan	104,168	—
Milestone payable	5,000,000	—
Total current liabilities	<u>6,621,309</u>	<u>2,015,083</u>
Long-term Liabilities:		
Note payable	2,000,000	—
Accrued interest payable	53,005	—
Total long-term liabilities	<u>2,053,005</u>	<u>—</u>
Total liabilities	<u>8,674,314</u>	<u>2,015,083</u>
Stockholders' equity:		
Common stock	2,633	2,443
Additional paid-in capital	94,691,151	90,108,492
Accumulated deficit	(96,617,199)	(85,730,390)
Total stockholders' (deficit) equity	<u>(1,923,415)</u>	<u>4,380,545</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 6,750,899</u>	<u>\$ 6,395,628</u>

Evoke Pharma, Inc.

Statement of Operations
(Unaudited)

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	\$ 205,032	\$ 822,444	\$ 6,450,979	\$ 2,774,924
General and administrative	1,874,578	814,218	4,387,284	2,955,371
Total operating expenses	<u>2,079,610</u>	<u>1,636,662</u>	<u>10,838,263</u>	<u>5,730,295</u>
Loss from operations	(2,079,610)	(1,636,662)	(10,838,263)	(5,730,295)
Other income (expense):				
Interest income	1,033	8,597	4,896	22,868
Interest expense	(50,528)	—	(53,442)	—
Total other income (expense), net	<u>(49,495)</u>	<u>8,597</u>	<u>(48,546)</u>	<u>22,868</u>

Net loss	<u>\$ (2,129,105)</u>	<u>\$ (1,628,065)</u>	<u>\$(10,886,809)</u>	<u>\$ (5,707,427)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.07)</u>	<u>\$ (0.43)</u>	<u>\$ (0.26)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>26,146,220</u>	<u>24,128,060</u>	<u>25,191,359</u>	<u>21,623,648</u>

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Source: Evoke Pharma, Inc.