VIVUS

VIVUS Shares Progress on Pipeline and Key Program Milestones During the 43rd Annual J.P. Morgan Healthcare Conference 2025

CAMPBELL, Calif., January 13, 2025, (GLOBE NEWSWIRE) – VIVUS LLC, a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs, today announced it will provide updates to its pipeline and key program milestones during the 43rd Annual J.P. Morgan Healthcare Conference 2025.

"VIVUS will be discussing its significant 2024 momentum during the J.P. Morgan Healthcare Conference, with an emphasis on what we as a company aim to achieve during the coming months around our novel therapies for exocrine pancreatic insufficiency, obesity and pulmonary arterial hypertension," said John Amos, Chief Executive Officer at VIVUS LLC. "Even with recent advancements in the overweight and obesity marketplace, our medication, QSYMIA®, continues to be a significant option for patients and we will continue our efforts to ensure the therapy is available globally. While the GLP-1s are important therapies, given their expense, complex side effect profile and that ~50% of patients leave the therapy in 6-12 months, patients, physicians and payors need other choices. We believe QSYMIA®/QSIVA® are important in that therapy selection process. QSYMIA®/QSIVA® sales have now exceeded $500M in gross revenue since 2020. As always, VIVUS LLC remains committed to addressing the needs of patients and advancing therapies that meet their unique needs."

Key 2024 highlights include:

- **Commercialization of QSIVA® (phentermine and topiramate modified-release) in all Scandinavian countries** (October 7, 2024): QSIVA is accessible to patients with overweight and obesity who could benefit from weight loss in Sweden, Denmark, Finland, Iceland, Norway, and Poland.
- **QSYMIA® (phentermine and topiramate extended-release capsules CIV) Label Update** (October 23, 2024): The label for QSYMIA was updated to remove specific body mass index (BMI) requirements and warnings or precautions regarding increase in heart rate, risk of hypoglycemia in people with type 2 diabetes taking antidiabetic therapy, and risk of hypotension in people taking antihypertensive medication.
- **The U.S. Food and Drug Administration removed the requirement for a cardiovascular outcome trial for QSYMIA** (October 28, 2024): The FDA determined that a cardiovascular outcome trial ("CVOT") is no longer necessary, stating that, as part of the Company's supplemental new drug application, the recent positive topline data from a postmarketing study evaluating the effect of QSYMIA on 24-hour ambulatory blood pressure (ABPM) (NCT05215418) does not raise concerns about cardiovascular risk and further assessment through a dedicated CVOT would not be additionally informative.
- **Positive data presented at the American Pancreatic Association highlighted the benefit of PANCREAZE® (pancrelipase) in pancreatic ductal adenocarcinoma patients with cachexia and exocrine pancreatic insufficiency** (December 9, 2024): PANCREAZE is feasible and well-tolerated in PDAC patients with cachexia and exocrine pancreatic insufficiency (EPI) who are treated with SOC chemotherapy.

- **Positive movement on increasing global availability of QSYMIA and QSIVA:** The Company is on track to launch its obesity management medication in 11 more European countries and the United Arab Emirates.

"VIVUS is also committed to progressing proprietary clinical programs that offer healthcare professionals new and innovative treatment options for their patients," said Santosh T. Varghese, MD, President VIVUS Global Pharmaceutical Development and Chief Medical Officer at VIVUS LLC. "Our carmustine program for relapsed or refractory non-Hodgkin lymphoma continues to advance on schedule with all clinical trial sites now registered and the first patient is expected to be enrolled during the first quarter of 2025. In addition, our discussions with the FDA about our pulmonary arterial hypertension (PAH) program are completed and we look forward to advancing the program."

QSYMIA is the leading non-injectable branded weight loss medication in the U.S. for adults. QSYMIA is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate, indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight in some adults and certain pediatric patients aged 12 years and older.

In addition to those affected by overweight and obesity, VIVUS has developed PANCREAZE to treat people with EPI. This affects many patient populations, including patients with cystic fibrosis, chronic pancreatitis, celiac disease, type 1 and type 2 diabetes, inflammatory bowel disease, and HIV infection. PANCREAZE is a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of EPI due to cystic fibrosis or other conditions. Patients living with EPI are unable to digest food normally, leading to stomach pain, gas, bloating, diarrhea, and other intestinal symptoms. PANCREAZE is now covered on 84% of commercial insurance plans, including preferred brand status on multiple plans. Additionally, PANCREAZE is available in six flexible dosing options to ensure tailored dosing for each patient's unique needs.

PAH is a degenerative and life-threatening disease that makes it difficult for the heart to pump blood to the lungs to be oxygenated and may ultimately lead to heart failure. Current PAH treatment options only address the symptoms, slowing but not preventing disease progression, which is why new therapies that address the underlying cause of disease are urgently needed. In January 2017, VIVUS acquired exclusive, worldwide rights to develop and commercialize tacrolimus and ascomycin for the treatment of PAH and related vascular diseases.

About VIVUS

VIVUS is a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. For more information about the Company, please visit http://www.vivus.com.

About QSYMIA

QSYMIA is indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12

VIVUS LLC, 900 E. Hamilton Avenue, Suite 550, Campbell, CA 95008 USA

www.vivus.com | 1-650-934-5200

years and older with obesity, and in adults with overweight in the presence of at least one weight-related comorbid condition.

The effect of QSYMIA on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of QSYMIA in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

For more information on QSYMIA, please visit https://QSYMIA.com/

About QSIVA

QSIVA (the European brand name for QSYMIA) is approved in Sweden, Denmark, Finland, Iceland, Norway, and Poland. QSIVA is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related medical condition such as high blood pressure, type 2 diabetes, or high cholesterol. The effect of QSIVA on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of QSIVA in combination with other products intended for weight loss, including prescription and over-the-counter drugs and herbal preparations, have not been established. For more information on QSIVA, please visit www.QSIVA.eu.

Important Safety Information for QSYMIA

Do not take QSYMIA if you are pregnant, planning to become pregnant, or become pregnant during QSYMIA treatment; have glaucoma; have thyroid problems (hyperthyroidism); are taking certain medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the past 14 days; are allergic to topiramate, sympathomimetic amines such as phentermine, or any of the ingredients in QSYMIA.

QSYMIA can cause serious side effects, including birth defects (cleft lip/cleft palate), serious eye problems (secondary angle closure glaucoma), visual field defects (independent of elevated intraocular pressure), suicidal thoughts or actions, and severe rash with blisters and peeling skin. QSYMIA may slow the increase in height in children 12 years and older.

Common side effects of QSYMIA in adults include numbness or tingling in the hands, arms, feet, or face (paraesthesia), dizziness, changes in the way foods taste or loss of taste (dysgeusia), trouble sleeping (insomnia), constipation, and dry mouth. Common side effects of QSYMIA in children aged 12 years and older include depression, dizziness, joint pain, fever, flu, and ankle sprain.

For more information, please read the QSYMIA Medication Guide, Full Prescribing Information, and Risk of Birth Defects with QSYMIA patient brochure.

Important Safety Information for QSIVA

QSIVA (phentermine and topiramate modified-release) hard capsules is contraindicated in pregnancy and in women of childbearing potential who are not using effective methods of contraception; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following

VIVUS LLC, 900 E. Hamilton Avenue, Suite 550, Campbell, CA 95008 USA

www.vivus.com | 1-650-934-5200

treatment with monoamine oxidase inhibitors; or in patients with hypersensitivity to sympathomimetic amines, topiramate, or any of the inactive ingredients in QSIVA.

QSIVA can cause fetal harm. It is recommended that patients who can become pregnant obtain a negative pregnancy test result before starting QSIVA treatment, perform monthly pregnancy testing, and use effective contraception while taking QSIVA. If a patient becomes pregnant while taking QSIVA, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most common adverse reactions in adults are paraesthesia, dizziness, an altered or impaired sense of taste, insomnia, constipation, and dry mouth.

About PANCREAZE

PANCREAZE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. PANCREAZE may help your body use fats, proteins, and sugars from food. PANCREAZE contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas. PANCREAZE is safe and effective in children when taken as prescribed by your doctor.

Important Safety Information for PANCREAZE

What is the most important information I should know about PANCREAZE?

- PANCREAZE may increase your chance of having a serious, rare bowel disorder called fibrosing colonopathy that may require surgery.
- The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you.

Call your doctor right away if you have any unusual or severe stomach area (abdominal) pain, bloating, trouble passing stool (having bowel movements), nausea, vomiting, or diarrhea.

Take PANCREAZE exactly as prescribed by your doctor. Do not take more or less PANCREAZE than directed by your doctor.

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- **A rare bowel disorder** called fibrosing colonopathy.
- **Irritation of the inside of your mouth.** This can happen if PANCREAZE is not swallowed completely.
- **Increase in blood uric acid levels**. This may cause worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels.
- **Allergic reactions** including trouble with breathing, skin rashes, or swollen lips.

VIVUS LLC, 900 E. Hamilton Avenue, Suite 550, Campbell, CA 95008 USA

www.vivus.com | 1-650-934-5200

Call your doctor right away if you have any of these symptoms.

The most common side effects include pain in your stomach (abdominal pain) and gas.

Other possible side effects: PANCREAZE and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs.

These are not all the side effects of PANCREAZE. Talk to your doctor about any side effect that bothers you or does not go away.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What should I tell my doctor before taking PANCREAZE?

Tell your doctor if you:

- are allergic to pork (pig) products.
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy).
- have gout, kidney disease, or high blood uric acid (hyperuricemia).
- have trouble swallowing capsules.
- have any other medical condition.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

The Product Information and Medication Guide for PANCREAZE is available at www.pancreaze.com.

Forward-Looking Statements

Important Information and Cautionary Note Regarding Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and/or covered by the "Bespeaks Caution" doctrine applied by the courts under the antifraud provisions of the federal securities laws, and other applicable provisions of the federal securities laws. Such forward-looking statements are based on current expectations, management's beliefs and certain assumptions made by the Company's management. These statements may be identified by the use of forward-looking words such as "will," "shall," "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "plan," "likely," "opportunity," "estimated," and "potential," and/or the negative use of these words or other similar words. All forward-looking statements

included in this document are based on our current expectations, and the Company assumes no obligation to update any such forward-looking statements except to the extent otherwise required by law.

Forward-looking information about QSYMIA, including its potential benefits, approvals in potential markets outside the U.S. and anticipated product availability, involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied in this press release. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any other markets or approved, whether QSYMIA will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of QSYMIA; uncertainties regarding the impact of COVID-19 on our business, operations, and financial results; and competitive developments.

The above factors, risks and uncertainties are difficult to predict, contain uncertainties that may materially affect actual results and may be beyond the Company's control. New factors, risks and uncertainties emerge from time to time, and it is not possible for management to predict all such factors, risks and uncertainties. Although the Company believes that the assumptions underlying the forward-looking statements contained herein are reasonable, any of the assumptions could be inaccurate, and therefore any of these statements may prove to be inaccurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by the Company or any other person that the Company's objectives and plans will be achieved. These forward-looking statements speak only as of the date such statements were made or any earlier date indicated, and the Company does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events, changes in underlying assumptions or otherwise, unless otherwise required by law.

Contacts

VIVUS LLC

T: +1 (650) 934-5200

Media – FINN Partners

Glenn Silver

glenn.silver@finnpartners.com
T: +1 973-818-8198