VIVUS Provides Update on Pipeline and Program Milestones

CAMPBELL, Calif., Jan. 08, 2024 (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 pipeline updates and program milestones.

“VIVUS has been continuously dedicated to addressing the therapeutic needs of patients with serious medical conditions and life-limiting diseases, including exocrine pancreatic insufficiency, obesity and pulmonary arterial hypertension,” said John Amos, Chief Executive Officer at VIVUS LLC. “While there have been several new entrants into the obesity market, we have been supporting patients seeking to achieve and maintain their healthy weight goals since QSYMIA® was approved more than a decade ago. QSYMIA® is now the number one branded oral product in the US for obesity treatment. As the obesity epidemic exacts tremendous health and economic costs around the globe, VIVUS is expanding our support of patients through the launch of QSYMIA®, which will be sold under the trade name QSIVA® in multiple European countries and sold under the trade name of QSYMIA® in the Middle East. VIVUS has a planned goal of providing access to QSYMIA® for a billion plus people across the globe by the end of 2025.”

Recently, VIVUS announced positive topline data from a post-marketing study to evaluate the effect of QSYMIA® (phentermine and topiramate extended-release capsules CIV) on 24-hour ambulatory blood pressure (ABPM) (#NCT05215418). This study, which enrolled patients who were diagnosed with obesity who also had at least one weight-related comorbidity, demonstrated that QSYMIA® treatment for eight weeks was associated with reductions in systolic blood pressure as assessed by ABPM compared to both placebo and phentermine.

QSYMIA®, in combination with a reduced-calorie diet and exercise, has been proven to help adults and children ages 12 - 17 lose weight and maintain the loss. The once-daily pill is covered by the majority (81%) of commercial healthcare plans and is indicated for long-term use.

Alongside weight management therapy, VIVUS also looks to improve the quality of life for patients diagnosed with exocrine pancreatic insufficiency (EPI), which 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.

"Our commitment to patients goes beyond bringing new therapies to market and includes making these therapies more convenient and easier to access," said Santosh T. Varghese, MD, President VIVUS Global Pharmaceutical Development and Chief Medical Officer at VIVUS LLC. "Toward this end, PANCREAZE is available in a 37,000-unit dose, which may be a convenient, appropriate option for many exocrine pancreatic insufficiency patients. Additionally, the shelf life of PANCREAZE has been extended to 36 months across all dosages. This allows patients to store the enzyme replacement therapy for longer periods of time, which may help in reducing out-of-pocket expenses."

"VIVUS also is committed to providing new therapeutic options to patients with pulmonary arterial hypertension," added Dr. Varghese. "Our lead pipeline program, VI-0106, is being developed to treat this debilitating and degenerative disease that makes it difficult for the heart to pump blood through the lungs to be oxygenated, which may ultimately lead to heart failure. Moreover, VIVUS is actively developing pipeline products focusing on bone marrow transplant preparation (VI-0609) and diabetes treatments (VI-0809 and VI-0810)."

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 and QSIVA

QSYMIA is approved in the U.S. and South Korea under the name QSYMIA and is approved in Sweden, Norway, Denmark, Finland, Iceland, and Poland under the name QSIVA. QSYMIA or 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/m^2 or greater (obese) or 27 kg/m^2 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. Only in the U.S., QSYMIA is also indicated in pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex. There is no corresponding approval for the EU yet.

The effect of QSYMIA or QSIVA on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of QSYMIA or 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. For more information about QSYMIA, please visit www.QSYMIA.com.

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.

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 Qysmia in children aged 12 years and older include depression, dizziness, joint pain, fever, flu, and ankle sprain.

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

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 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.

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