VIVUS

VIVUS Announces Label Update for QSYMIA®

– QSYMIA® is the leading once-daily oral branded, weight-management medication –

– First head-to-head randomized placebo-controlled study of QSYMIA® and phentermine demonstrating reductions in ambulatory blood pressure (ABPM) –

– New label removes strict requirements of BMI for patient eligibility –

CAMPBELL, Calif., October 23, 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 the United States Food and Drug Administration (FDA) approved a labeling update for QSYMIA® (phentermine and topiramate extended-release capsules CIV). This update removed 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 anti-diabetic therapy, and risk of hypotension in people taking antihypertensive medication.

“Over the last 12 years, we have watched QSYMIA positively improve quality of life and assist with weight loss, in combination with a healthy diet and consistent exercise. QSYMIA is now approved and available in the United States, South Korea, Sweden, Norway, Poland, Denmark, Iceland, and Finland. The product was recently approved in United Arab Emirates and VIVUS is anticipating approvals in additional European and Middle Eastern countries,” said John Amos, Chief Executive Officer at VIVUS LLC.

Amos continued, “One in five adults and 1 in 4 young adults (12-17) experiences weight loss of at least 20% of their body weight on high dose. Now, with its new label, we have the opportunity to reach a number of people who may not have previously qualified for QSYMIA to achieve and maintain their long-term weight goals. The approval of this new label reflects the positive outcome of our ongoing and productive dialogue with the FDA, which shares our commitment to addressing unmet medical needs surrounding overweight and obesity.”

The revised QSYMIA label includes data from the first head-to-head, randomized, double-blind clinical trial of phentermine. The post-marketing study assessed ambulatory blood pressure (ABPM) for eight weeks in patients with overweight or obesity who also had at least one weight-related comorbidity (i.e., hypertension, dyslipidemia, impaired fasting glucose or glucose tolerance, type 2 diabetes mellitus, or obstructive sleep apnea). Key findings from this study include:

- The placebo-adjusted difference in systolic blood pressure was –3.2 mmHg for QSYMIA and +1.5 mmHg for phentermine, corresponding to a mean treatment difference of –4.7 mmHg for QSYMIA.
- The placebo-adjusted difference in diastolic blood pressure was +1.2 mmHg for QSYMIA and +2.7 mmHg for phentermine, corresponding to a mean treatment difference of –1.5 mmHg for QSYMIA.
- The placebo-adjusted difference in heart rate was +3.6 beats per minute (bpm) for QSYMIA and +7.2 bpm for phentermine, corresponding to a mean treatment difference of –3.6 bpm for QSYMIA.

Obesity is linked to major causes of death, including heart disease, stroke, and diabetes. With an estimated one billion people worldwide to be affected by obesity by 2030, an almost two-fold increase from its 2020 prevalence of approximately 511 million, medical communities and health care providers are adopting evolving perspectives on defining how to qualify patients with overweight or obesity. While BMI remained a key benchmark for developing weight management plans, it did not always account for patients with weight-related comorbidities nor allow for providers to optimize results based on a number of success indicators.

BMI can vary significantly across different populations due to a range of factors, including genetics, cultural dietary habits, socioeconomic conditions, and lifestyle behaviors. For example, the World Health Organization (WHO) has shared scientific evidence that suggests Asian populations have different associations between BMI, percentage of body fat, and health risks than European populations.[i] One expert consultation concluded that the proportion of Asian people with a high risk of type 2 diabetes and cardiovascular disease is substantial at BMIs lower than the existing WHO cut-off point for overweight (> or =25 kg/m2).[ii]

“The updated QSYMIA label simplifies physician decision-making by removing specific BMI targets, enabling greater flexibility and empowering physicians to develop customized treatment plans that support weight loss, have favorable effects on blood pressure, and give patients a choice of treatment modality,” said Santosh T. Varghese, MD, President VIVUS Global Pharmaceutical Development and Chief Medical Officer at VIVUS LLC. “We believe that QSYMIA provides a differentiated and highly defined safety and efficacy profile with over 12 years of experience in the United States that can help patients achieve and maintain their healthy weight goals without the need for daily injections.”

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.

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The once-daily pill is currently covered by 81% of commercial healthcare plans and is indicated for long-term use. QSYMIA is designed to help patients manage hunger and reduce cravings throughout the day and, combined with a healthy diet and exercise, has been proven to help patients lose, and maintain, weight loss.

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 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/

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.

Forward-Looking Statements

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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.

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[i] WHO Expert Consultation (2004). Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies. *Lancet (London, England)*, *363*(9403), 157–163. https://doi.org/10.1016/S0140-6736(03)15268-3

[ii] Li, Z., Daniel, S., Fujioka, K., & Umashanker, D. (2023). Obesity among Asian American people in the United States: A review. *Obesity (Silver Spring, Md.)*, *31*(2), 316–328. https://doi.org/10.1002/oby.23639