New Clinical Data Demonstrate that QSYMIA®, the Leading Once-Daily Oral Weight-Management Medication, Reduces Blood Pressure

CAMPBELL, Calif., Nov. 28, 2023 (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 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 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) 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. Obesity and high blood pressure are significant risk factors for the development of cardiovascular disease.

“A challenge for patients and clinicians is that anti-obesity medications have variable effects on blood pressure; this is a clinically relevant consideration given that high blood pressure is a major cardiovascular disease risk factor,” said Dr. Harold Bays, Medical Director and President of the Louisville Metabolic and Atherosclerosis Research Center, and a Principal Investigator for this trial. “This data supports that beyond beneficial effects of reducing body weight, QSYMIA also favorably affects blood pressure – a common and important health metric.”

VIVUS currently is discussing the results of the double-blind study conducted in 565 overweight/obese adult subjects who were randomized (1:1:1) to an eight-week course of once-daily placebo, QSYMIA (15 mg phentermine/92 mg topiramate) or phentermine (30 mg) with the U.S. Food & Drug Administration and expects to present or publish the complete study results in a peer-reviewed forum.

“When selecting from a growing number of weight loss medication options, most of which are injectables, it is important for patients and physicians to consider efficacy, safety, ease of use, and financial cost, and to choose an option that gives each patient the best chance

of achieving and maintaining their long-term healthy weight goals," said Santosh T. Varghese MD, President VIVUS Global Pharmaceutical Development and Chief Medical Officer at VIVUS LLC. "QSYMIA offers a differentiated profile consisting of demonstrated efficacy with respect to weight loss and blood pressure reduction, well-defined safety, convenient once-daily oral administration, and cost-effectiveness. We believe this combination of attributes, which is backed by multiple clinical trials and 11 years of real-world use, is the reason that QSYMIA is the leading oral weight management medication."

The Institute for Clinical and Economic Review's (ICER) Evidence Report, dated August 2022, assessed the comparative clinical effectiveness and value of treatments for obesity management. Results showed that VIVUS' QSYMIA was more cost effective for weight loss than other weight loss drugs, including newer injectable medications.[i]

QSYMIA is the leading non-injectable weight loss medication in the U.S. for adults. QSYMIA is indicated as an FDA-approved adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in some adults and certain pediatric patients aged 12 years and older. The once-daily pill is currently covered by the majority (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.

Obesity is a global epidemic. It is estimated that one billion people worldwide will be affected by obesity by 2030. This represents almost a two-fold increase from its 2020 prevalence of approximately 511 million. Importantly, obesity increases the risk of type 2 diabetes, hypertension and dyslipidemia, thereby increasing the risk of cardiovascular disease and mortality.

About QSYMIA
QSYMIA is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate, 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 comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. QSYMIA may also be used in pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex.

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 and over-the-counter drugs, and herbal preparations, have not been established.

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

Important Safety Information

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 QSYMIA 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.

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.

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.

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