VIVUS

VIVUS Shares Significant Regulatory Update on QSYMIA®

- *Postmarketing requirement fulfilled based on data demonstrating QYSMIA® reduces blood pressure* -

CAMPBELL, Calif., October. 28, 2024 (GLOBE NEWSWIRE) – VIVUS announced today that the U.S. Food and Drug Administration has removed the requirement for a cardiovascular outcome trial for its weight-management medication QSYMIA (phentermine and topiramate extended release capsules) CIV.

In a letter to the Company, 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.

"Following the recently announced positive news of the QSYMIA label update, which removed strict requirements of BMI for patient eligibility, we are thrilled to receive this response from the FDA, releasing VIVUS from conducting additional cardiovascular outcomes trials," said Dr. Santosh Varghese, President VIVUS Global Pharmaceutical Development & Chief Medical Officer of VIVUS. "With strong data from our ABPM study, this milestone reflects our commitment to working with the FDA to demonstrate the differentiated and highly defined safety and efficacy profile of QSYMIA in helping patients achieve and maintain their healthy weight goals."

The postmarketing study assessed 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). The study demonstrated that QSYMIA treatment for eight weeks was associated with reductions in 24-hour mean systolic blood pressure as assessed by ABPM compared to both placebo and phentermine. This is the first head-to-head randomized, double-blind clinical trial to evaluate effects of relevant doses of QSYMIA and phentermine on blood pressure. Phentermine is the most widely prescribed anti-obesity medication in the US market with over 8M prescriptions according to IQVIA data.

Approved by the U.S. FDA in 2012, 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.

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.

By 2030, it's projected that obesity will impact one billion people worldwide. This marks nearly a twofold increase from around 511 million in 2020. Significantly, obesity escalates the risk of type 2 diabetes, hypertension, and dyslipidemia. Consequently, this heightened risk contributes to an overall increased

susceptibility to cardiovascular disease and mortality. Achieving and maintaining healthy weight goals can play a crucial role in mitigating this risk.

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

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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