FDA Approves QSYMIA® for the Treatment of Obesity in Adolescents Ages 12-17

CAMPBELL, Calif., July 20, 2022 (GLOBE NEWSWIRE) -- VIVUS LLC today announced that the U.S. Food and Drug Administration (FDA) approved QSYMIA (phentermine and topiramate extended-release capsules) CIV for use in the treatment of obesity in adolescents (12-17 years old) with an initial body-mass index (BMI) in the 95th percentile or greater standardized for age and sex. According to the CDC, approximately 22% of children aged 12-19 years in the United States — about 14 million individuals — have obesity.

The results of the QSYMIA Phase 3 trial in adolescent patients taking the top-dose demonstrated that more than 44% of patients lost at least 15% of their body weight and more than 30% of patients lost at least 20% of their body weight.

"Up to 90 percent of adolescents with obesity are likely to have obesity as adults, putting them at increased risk for developing weight-related complications," said Dr. Aaron Kelly, Professor of Pediatrics and co-director of the Center for Pediatric Obesity Medicine at the University of Minnesota. "Consequently, it is important to address weight care and offer support early on. New options to treat adolescents who live with obesity can bring much-needed hope to families and help address this growing epidemic, and the approval of QSYMIA in this patient population gives healthcare providers a new tool for developing personalized, complete care plans to help adolescents lose weight and keep it off."

Adolescence is a critical period for the development of obesity. Obesity arises from a complex interaction among numerous factors, including a strong biological component. The increased prevalence of adolescent obesity in the United States and its associated short- and long-term complications underscore the need for safe and effective treatment. Chronic obesity-related health conditions such as type 2 diabetes, insulin resistance, hypertension, dyslipidemia, obstructive sleep apnea and fatty liver disease, were previously only seen in adults but are now being diagnosed with increasing frequency in adolescents. Obesity also diminishes adolescents' quality of life, and excess adiposity often carries into adulthood.

"As a company committed to innovating new solutions for the obesity crisis, the FDA approval of QSYMIA for the treatment of obesity in adolescents is an important milestone for our

dedicated team," said Dr. Santosh T. Varghese, Senior Vice President, Chief Medical Officer of VIVUS LLC. "It also is an important advancement for the patients and physicians who face the daily personal and public health challenges that result from the rise in adolescent obesity. One of these challenges is the limited treatment options for adolescents with obesity, and we are gratified that our continued evaluation of QSYMIA in specific patient populations has resulted in a new FDA-approved therapy in this indication."

"VIVUS is committed to ensuring that any patient or physician who desires an oral solid medication for therapeutic-induced weight loss will have access to QSYMIA, one of the most cost-effective branded pharmaceutical obesity therapies," said John Amos, CEO of VIVUS LLC. "QSYMIA already is approved in eight countries, and we will continue to pursue additional approvals to increase patient access."

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 approved in the U.S. and 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, and 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 about QSYMIA, please visit www.QSYMIA.com.

Important Safety Information

QSYMIA (phentermine and topiramate extended-release capsules) CIV is contraindicated in pregnancy; 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 QSYMIA.

QSYMIA can cause fetal harm. It is recommended that patients who can become pregnant obtain a negative pregnancy test result before starting QSYMIA treatment, perform monthly pregnancy testing, and use effective contraception while taking QSYMIA. If a patient becomes pregnant

while taking QSYMIA, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most common adverse reactions reported in the pediatric clinical trial included depression, dizziness, arthralgia, pyrexia, influenza, and ligament sprain. The most common adverse reactions in adults are paraesthesia, dizziness, an altered or impaired sense of taste, insomnia, constipation, and dry mouth.

About the Phase 3 Trial

The data supporting the FDA approval of QSYMIA in treating obesity in adolescents demonstrated a significant reduction in BMI, mean body weight and other weight-related endpoints compared placebo in adolescents with obesity when using QSYMIA as an adjunct to lifestyle therapy. 44% of patients in the top-dose QSYMIA group who completed the adolescent QSYMIA study lost at least 15% of their body weight and over 30% lost at least 20% of their body weight. The incidence of participants reporting at least one adverse event was 51.8%, 37.0%, and 52.2% in the placebo and mid- and top-dose QSYMIA groups, respectively. Overall, three serious adverse events were reported in two participants, both of whom were in the top-dose QSYMIA group.

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, an approval in 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 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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