

New Clinical Data Demonstrate that VIVUS' QSYMIA[®] in Combination with Digitally Enhanced Lifestyle Interventions (DELI) Leads to Significantly Greater Reductions in Weight and Cardiovascular Risk Compared with DELI Alone in Adults with Obesity

— Participants in the combined treatment group lost significantly more weight at 3, 6, and 12 months and were more likely to lose 5%, 10%, or $\geq 15\%$ of their body weight at 12 months compared with DELI alone

CAMPBELL, Calif., Jan. 26, 2026, (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 results of a randomized trial ([NCT04408586](#)) evaluating the effect of QSYMIA[®] (phentermine and topiramate extended-release capsules CIV) in combination with DELI compared to DELI plus placebo on weight loss and cardiovascular disease risk outcomes in adults with obesity. Results show that QSYMIA in combination with DELI significantly improved weight loss, percentage of body weight lost, and atherosclerotic cardiovascular disease (ASCVD) risk compared with DELI plus placebo. The results are published in [Obesity](#).

"This study shows a positive effect of an anti-obesity medication in combination with digital lifestyle intervention on body weight in adults with obesity," said Andres Acosta, M.D., Ph.D., principal investigator for the study at Mayo Clinic in Rochester, Minnesota. "The data demonstrate that the combination of QSYMIA and digital lifestyle intervention showed improvements in cardiovascular disease risk markers and other metabolic parameters compared with digital lifestyle intervention alone. Given that patients with obesity face significant health risks, including cardiovascular risk, these results provide important insights into treatment approaches that may help individuals achieve weight loss goals while addressing cardiovascular health."

The 12-month, single-center, double-blinded, randomized trial examined the effect of QSYMIA (7.5/46mg) or placebo, each in combination with DELI, on weight loss and ASCVD risk. Participants received an activity-tracking wearable device, a digital weight scale and blood pressure cuff, and access to a smartphone application for the DELI. A total of 80 participants were randomized (QSYMIA n=42, placebo n=38). The primary endpoint was total body weight loss at 3-months. Key study results include:

- Among the 90% of participants who completed 3 months of study, significantly more weight was lost in the QSYMIA plus DELI group compared with the placebo plus DELI group (-10.82 kg vs. -4.04 kg, P=0.002).
- Among the 66% of participants who completed 12 months of study, significantly more weight was lost in the QSYMIA plus DELI group compared with the placebo plus DELI group (-15.32 kg vs. -5.85 kg, P<0.001).
- Participants in the QSYMIA group were more likely than those in the placebo group to lose $\geq 5\%$ (100% vs. 42%), $\geq 10\%$ (83% vs. 11%), and $\geq 15\%$ or more (43% vs. 5%) of baseline body weight at 12 months.
- Participants in the QSYMIA plus DELI group had a 3.35% reduction in lifetime ASCVD risk compared with those in the DELI plus placebo group (P=0.004).
- Participants in the QSYMIA plus DELI group also had greater reductions compared with those in the placebo plus DELI group in waist circumference (-12.6 vs -2.07, P<0.001), body mass index (-5.07 kg/m² vs. -1.88 kg/m²), and diastolic blood pressure (-4.79 mm Hg vs. -1.16 mm Hg, P=0.048).

“The results of this study add to the growing body of data demonstrating that QSYMIA remains an important treatment option in an evolving weight management landscape,” said Santosh T. Varghese, MD, President of VIVUS Global Pharmaceutical Development and Chief Medical Officer at VIVUS LLC. “For many people, lifestyle interventions – digital or otherwise – simply aren’t enough to overcome the biological drivers of obesity. QSYMIA has a demonstrated track record of efficacy and safety, can be taken orally, and may be a more cost-effective option than injectable anti-obesity medications. With these attributes, we believe that QSYMIA can be the foundation of tailored weight management regimens that meet patients’ needs.”

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.

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.

Additional risks and uncertainties specific to this pricing program announcement include: the risk that the reduced pricing program may not achieve anticipated patient enrollment or utilization levels at participating Costco Pharmacy locations in Hawaii; the possibility that competitive pricing actions, changes in the obesity treatment landscape, or regulatory developments could impact program effectiveness; and uncertainties regarding the accuracy of obesity prevalence projections cited for Hawaii, including the projected increase to 52% by 2030, which may differ materially from actual rates. The program's success depends on factors including consumer awareness, healthcare provider adoption, operational execution at the participating Costco locations, and the Company's ability to balance the financial impact of reduced pricing with strategic access objectives. Economic conditions, changes in Costco's business operations, or unforeseen supply chain challenges could also affect program delivery and outcomes.

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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