VIVUS' QSIVA in Combination with a Digital Lifestyle Intervention Leads to Significant Weight Loss and Decreased Cardiovascular Risk in Patients with Obesity

— Poster presented at the 30th European Congress on Obesity (ECO 2023) shows addition of QSIVA provides benefits compared with Digital Lifestyle Intervention (DLI) alone in improving health outcomes in adults with obesity —

AMSTERDAM, Netherlands, May 17, 2023 (GLOBE NEWSWIRE) -- VIVUS BV, the European affiliate of VIVUS LLC ("**VIVUS**"), a biopharmaceutical company, today announced the results of a clinical study (NCT04408586) demonstrating that QSIVA (phentermine and topiramate modified-release) hard capsules in combination with a DLI resulted in significantly greater weight loss and cardiovascular risk reduction in patients with obesity compared with the DLI alone.

Andres Acosta, MD, PhD, Associate Professor of Medicine and Principal Investigator of the Precision Medicine for Obesity Laboratory at Mayo Clinic, will present initial results of the study on May 17, 2023 in a poster (Abstract #PO4.121) at ECO 2023, which will take place in Dublin, Ireland, May 17-20.

Key findings from the study show that:

- The mean weight loss at 3 months was 9.99 kg (9.25 % of baseline weight) QSIVA, as compared with 3.62 kg (3.27%) in the placebo group (P=0.001), demonstrating a 2.82-fold increase in percent body weight loss for the QSIVA group compared with DLI alone.
- At 12 months, participants in the QSIVA group had a 14.08 kg weight loss (13.0% of baseline body weight) compared with 4.64 kg (4.20%) in the placebo group (P<0.001), demonstrating a 3.10-fold increase in percent body weight loss for the QSIVA group compared with DLI alone.

- There were no differences in all physical activity data (i.e., daily steps, heart rate, blood pressure, burned calories) collected using the wearables between both groups ($p > 0.05$).

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.

“In the current study, there was substantially greater weight loss for participants using QSIVA and the DLI compared with previous studies of QSIVA without a DLI,” said Dr. Santosh T. Varghese, President Global Development & Chief Medical Officer. “Taken with the increased weight loss in the QSIVA arm of the current study, these results suggest that the combination therapy provides synergistic benefit compared with QSIVA or the DLI alone. This finding is consistent with our understanding of obesity as a multifactorial disease that requires a multifaceted approach. The data reinforce the important role that QSIVA may play as part of tailored, combination regimens that help patients achieve their healthy weight goals.”

The combination of phentermine and topiramate is approved in Sweden, Norway, Denmark, Finland, Iceland and Poland under the name QSIVA ([phentermine and topiramate modified-release] hard capsules) and in the United States and South Korea as QSYMIA ([phentermine and topiramate extended-release capsules] CIV).

About the Study
The data reported today are from a 12-month, randomized, double-blind, single-center trial, in which 80 adults with obesity were enrolled in a DLI program and randomized to either QSIVA (7.5 mg/46 mg) (n=42) or placebo (n=38). Participants received an activity-tracking wearable device, a Bluetooth-enabled digital weight scale and digital blood pressure cuff, and access to a smartphone application. Subjects participated in eight in-person and eight telehealth visits over the 12-month study period. At the time of randomization, participants received counseling on the lifestyle intervention, which included a low-calorie diet, 10,000 daily steps, 150 minutes of exercise each week, no liquid calories or artificial sweeteners, and daily self-recording of blood pressure. The primary endpoint was total body weight loss at 3 months.

Poster Presentation Information
Title: Effects of Digital-Enhanced Lifestyle Intervention Combined with Phentermine-Topiramate or Placebo on Weight Loss and Cardiovascular Risk Outcomes: A 12-month Single-Centre Double-blind Randomized Trial
Presentation Date: May 17, 2023
Presentation Location: Exhibition Area

About QSYMIA and QSIVA
QSYMIA is approved in the U.S. and South Korea under the name QSYMIA and is approved in Sweden, Norway, Denmark, Finland, Iceland, and Poland under the name QSIVA. QSYMIA or QSIVA 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. Only in the U.S., QSYMIA is also indicated in pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex. There is no corresponding approval for the EU yet.

The effect of QSYMIA or QSIVA on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of QSYMIA or QSIVA 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 QSIVA, please visit www.QSIVA.eu. For more information about QSYMIA, please visit www.QSYMIA.com.

Important Safety Information for QSIVA
QSIVA (phentermine and topiramate modified-release) hard capsules is contraindicated in pregnancy and in women of childbearing potential who are not using effective methods of contraception; 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 QSIVA.

QSIVA can cause fetal harm. It is recommended that patients who can become pregnant obtain a negative pregnancy test result before starting QSIVA treatment, perform monthly pregnancy testing, and use effective contraception while taking QSIVA. If a patient becomes pregnant while taking QSIVA, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most common adverse reactions in adults are paraesthesia, dizziness, an altered or impaired sense of taste, insomnia, constipation, and dry mouth.

Important Safety Information for QSYMIA
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 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 or QSIVA, 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 or QSIVA 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 or QSIVA; 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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