VIVUS Announces Commercialization of QSIVA® in Sweden, Denmark, Finland, Iceland, Norway, and Poland

— QSIVA now available in all Scandinavian countries —

AMSTERDAM, Netherlands, October 7, 2024 — VIVUS BV, a subsidiary of VIVUS LLC, today announced the availability of QSIVA® (phentermine and topiramate modified-release) in Sweden, Denmark, Finland, Iceland, Norway, and Poland, making QSIVA accessible to patients with overweight and obesity who could benefit from weight loss.

“Obesity and being overweight, which comprise a substantial and growing epidemic, are significant risk factors for a number of serious health conditions, including heart disease, diabetes, joint pain, and mobility issues,” said André Heikius, MD, M.Sci, Founder and Medical Director, Suomen Painoklinikka, Turku, Finland. “The availability of a new weight-loss medication that acts through a different mechanism of action than other approved therapies will allow physicians to work with patients to develop tailored strategies and treatment regimens that can help them reach and maintain their healthy weight goals.”

The approval in the Scandinavian countries and Poland was supported by compelling Phase III clinical data from more than 3,700 patients who participated in the EQUIP (#NCT00554216) and CONQUER (#NCT00553787) trials, which demonstrated that subjects assigned to treatment with QSIVA achieved 7.8 - 10.9 percent weight reduction (ITT-analysis) and 7.6 - 10.9 cm reduction of waist circumference after 56 weeks of treatment.

The combination of phentermine (a sympathomimetic amine anorectic) and topiramate extended-release (an oral agent used to treat a variety of neurologic conditions) has been supporting patients seeking to achieve and maintain their healthy weight goals for over a decade in the United States, which is sold under the trade name QSYMIA® (phentermine and topiramate extended-release capsules CIV) by VIVUS LLC. As the number one branded oral product in the U.S. for obesity treatment, more than 4 million prescriptions have been written for QSYMIA, providing a substantial base of real-world evidence underlying the efficacy, safety, and tolerability of phentermine and topiramate. QSYMIA was also launched in the Republic of Korea in 2020.

The projected global impact of obesity is staggering, with an estimated one billion people expected to be affected by 2030. This marks nearly a twofold increase from the 2020 prevalence of around 511 million. Significantly, obesity escalates the risk of type 2 diabetes, hypertension, and dyslipidaemia. 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.

“VIVUS continues to deliver on our commitment to helping patients with overweight and obesity by making our weight management therapies available to more patients worldwide,” said Dr. Santosh Varghese, President VIVUS Global Pharmaceutical Development & Chief Medical Officer of VIVUS. “With the availability of QSIVA across all Scandinavian nation and Poland, and QSYMIA already supporting patients in the Republic of Korea and the U.S., VIVUS looks to continue expanding access to patients globally with a planned launch of QSYMIA in the Middle East. By the end of 2025, our goal is to provide access to QSIVA and QSYMIA to one billion plus people across the globe.”

“Today marks a significant milestone for VIVUS, physicians and their patients as we are now able to bring our effective, convenient and safe treatments to a new audience and help even more individuals achieve their health and wellness goals,” said Alessandro Giacometti, VIVUS Vice President and Managing Director Europe. “QSIVA is a clinically proven weight management option to treat the complex, multifactorial disease that is obesity, as shown by the Phase 3 clinical trial results. We look forward to the availability of QSIVA for European patients in the years to come.”

Subjects who were treated with QSIVA for the full 56-week study period (completer on drug analysis) achieved 9.6 – 14.4 percent weight reduction and 9.4 – 13.6cm reduction of waist circumference after completion of treatment. These clinical trials also demonstrated that phentermine/topiramate in combination with a weight-loss diet and exercise program resulted in statistically significant and clinically important reductions vs. placebo in weight and waist circumference, coupled with improvements in important risk markers indicative of weight-related comorbidities, such as systolic and diastolic BP, triglycerides, fasting glucose and progression towards type 2 diabetes.

Data from the SEQUEL trial (#NCT00796367), a 52-week extension of the CONQUER study, show that subjects assigned to treatment with the mid- and top-doses of QSIVA achieved 7.5 and 8.7 percent greater weight reduction than placebo, respectively, after two years of treatment. Moreover, subjects treated with QSIVA maintained an improved metabolic profile despite reduced concomitant antihypertensive, antidiabetic, and lipid-lowering medications compared to those treated with placebo.

In October 2019, VIVUS announced that European regulatory agencies in Sweden (Reference Member State), Denmark, Finland, Iceland, Norway, and Poland (the “Concerned Member States”) had accepted the Marketing Authorization Application (the “MAA”) for QSIVA on a decentralized basis, with Sweden acting as the lead Concerned Member State, also known as the Reference Member State, for purposes of assessing the MAA. Under the decentralized MAA procedure, the regulatory authorities in each of the Concerned Member States may simultaneously provide Marketing Authorization for use of a product within those specific countries.

QSIVA is currently undergoing the Regulatory assessment seeking marketing authorization in 12 additional European countries.

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 QSIVA

QSIVA (the European brand name for QSYMIA) is approved in Sweden, Denmark, Finland, Iceland, Norway, and Poland. 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/m2 or greater (obese) or 27 kg/m2 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.

The effect of QSIVA on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of 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.

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 a 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 for QSIVA
QSIVA (phentermine and topiramate modified-release) hard capsules are 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
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 Qysmia 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.

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