

KVK Tech, Inc. Announces Partnership with Medix for International Expansion into Mexico

NEWTOWN, PA., Nov 14, 2017 /PRNewswire/ -- KVK Tech, Inc. (KVK), a leading American developer, manufacturer, and marketer of FDA-approved pharmaceuticals today announced a strategic partnership with Productos Medix S.A. de C.V. ("Medix"), a leader in pharmaceutical obesity products in Mexico. The licensing agreement awards Medix a license for the manufacture, distribution, and marketing of Lomaira™ (phentermine hydrochloride USP) 8 mg tablets, CIV in Mexico.

Lomaira is an appetite suppressant available by prescription only and used for a short period of time for weight reduction in adults with an initial body mass index (BMI) of 30 or more or 27 or more with a weight-related condition such as controlled high blood pressure, diabetes, or high cholesterol. BMI measures the amount of fat in the body based on height and weight and is measured in kg/m². Lomaira should be used together with increased physical activity and a reduced-calorie diet. Please see full prescribing information for Lomaira at www.lomaira.com.

Medix plans to work with its current, extensive physician network and portfolio of more than 10 products for weight loss. According to Mario Lazcano, Legal VP of Medix, the current market for prescription medicine for obesity in Mexico is about US\$ 250 million. The licensing agreement includes milestone payments and royalties to be paid to KVK.

"We're thrilled to partner with Medix, a trusted leader in the obesity space in Mexico, as it allows KVK to expand into international markets and open a new channel of distribution in the weight-loss industry," said Kiran Vepuri, Director of Business Development at KVK. "Mexico has the second largest population with obesity in the world and Lomaira offers patients another weight-loss treatment option to meet their lifestyle needs."

Lomaira is a low dose of the #1 prescribed medicine for weight loss in the U.S. for nearly 60 years (phentermine). Now the flexible dosing options of Lomaira provide a unique opportunity for patients to take a modest dose when they need it, especially before the evening meal when appetite is the greatest¹. Unlike the higher strengths of phentermine HCl that are dosed once a day before or shortly after breakfast, Lomaira is FDA-approved to be used up to 3x daily before each meal.²

IMPORTANT SAFETY INFORMATION

Don't take Lomaira™ if you have a history of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure or uncontrolled high blood pressure); are taking or have taken a monoamine oxidase inhibitor drug (MAOI) within the past 14 days; have overactive thyroid, glaucoma (increased pressure in the eyes), agitation or a history of drug abuse; are pregnant, nursing, or allergic to the sympathomimetic amines such as phentermine or any of the ingredients in Lomaira.

Taking phentermine with other drugs for weight loss is not recommended. Primary pulmonary hypertension (PPH), a rare fatal lung disease, has been reported in patients who had taken a combination of phentermine and fenfluramine or dexfenfluramine for weight loss. The possible association between phentermine use alone and PPH cannot be ruled out. Patients should report immediately if they experience any decrease in the amount of exercise that they can normally tolerate, shortness of breath, chest or heart pain, fainting or swelling in the lower legs.

Serious heart valve problems or disease have been reported in patients taking a combination of phentermine and fenfluramine or dexfenfluramine for weight loss. The possible role of phentermine has not been

established, therefore the possibility of an association between heart valve disease and the use of phentermine alone cannot be ruled out.

If your body becomes adjusted to the maximum dose of phentermine so that its effects are experienced less strongly, the maximum dose should not be exceeded in an attempt to increase the effect.

Caution is advised while engaging in potentially hazardous activity such as driving or operating machinery while taking phentermine. Phentermine has the potential to be abused. Keep Lomaira in a safe place to prevent theft, accidental overdose, misuse or abuse. Using alcohol with phentermine may result in an adverse drug reaction.

Phentermine can cause an increase in blood pressure. Tell your doctor if you have high blood pressure, even if it's mild. If you are taking medicines for type 2 diabetes, your doctor may have to adjust these medicines while taking phentermine.

Some side effects of phentermine that have been reported include pulmonary hypertension, valvular heart disease, palpitations, increased heart rate or blood pressure, insomnia, restlessness, dry mouth, diarrhea, constipation and changes in sexual drive. These are not all of the potential side effects of phentermine. For more information, ask your doctor or pharmacist.

To report negative side effects of prescription drugs, contact FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

See Full Prescribing Information at www.lomaira.com.

About KVK Tech

KVK is a leader in the development and manufacture of high-quality, FDA-approved medicines that address unmet patient needs. Founded in 2004, KVK takes pride in its ability to advance medical care and offer low-cost alternatives in response to today's healthcare challenges. All of KVK's products are made in the U.S.A. in a state-of-the-art facility in Newtown, PA. KVK is committed to maintaining its entire business operations in America, as it continues to build strong, lasting relationships with the nation's largest pharmacy chains, wholesalers and distributors.

¹ Obesity (2013), 21, 421-423, doi:1002/oby.20351

² Lomaira package insert, Newtown, PA

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