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VIVUS Announces License and Commercialization Agreement With Sanofi for Avanafil in Africa, Middle East, Turkey and CIS/Russia

MOUNTAIN VIEW, Calif., Dec. 12, 2013 (GLOBE NEWSWIRE) -- VIVUS, Inc. (Nasdaq:VVUS) today announced that it has entered into a License and Commercialization Agreement with Sanofi to commercialize avanafil on an exclusive basis in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the tradename SPEDRA™ or STENDRA™.

Under the terms of the agreement, VIVUS is eligible to receive up to $61 million in upfront payments, regulatory and sales milestones. VIVUS will also receive escalating royalties based on net sales over the life of the agreement.

"Sanofi is an established leader in emerging markets and a valued partner for VIVUS," said Seth H. Z. Fischer, CEO of VIVUS, Inc.

In July 2013, VIVUS announced an exclusive license with the Menarini Group to commercialize avanafil in Europe, Australia and New Zealand. In October 2013, VIVUS announced an exclusive license with Auxilium Pharmaceuticals, Inc. to commercialize avanafil in the United States and Canada. Under the Menarini, Auxilium and Sanofi agreements, avanafil is expected to be commercialized in over 100 countries worldwide.

"We are pleased with the alliance we have forged with our partners at Sanofi," stated John L. Slebir, vice president, business development and general counsel of VIVUS, Inc. "This agreement is another key accomplishment for VIVUS in the monetization of avanafil."

Aquilo Partners, L.P. acted as the exclusive advisor to VIVUS on the transaction.

About Avanafil

SPEDRA™, the trade name for avanafil in the EU and certain other territories outside of the U.S., has been approved by the EMA for the treatment of erectile dysfunction in the EU.

STENDRA™, the trade name for avanafil in the U.S. and certain other territories, is approved by the FDA for the treatment of erectile dysfunction in the U.S. Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual dysfunction, with the exception of certain Asian-Pacific Rim countries.

VIVUS has granted an exclusive license to the Menarini Group through its subsidiary Berlin-Chemie AG to commercialize and promote SPEDRA for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand. VIVUS has granted an exclusive license to Auxilium Pharmaceuticals, Inc. to market STENDRA in the United States and Canada. VIVUS has granted an exclusive license to Sanofi to commercialize avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia. VIVUS is currently in discussions with potential partners to commercialize STENDRA in its remaining territories.

For more information about STENDRA, please visit www.Stendra.com.

Important Safety Information

STENDRA™ (avanafil) is prescribed to treat erectile dysfunction (ED).

Do not take STENDRA if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure.

Discuss your general health status with your healthcare provider to ensure that you are healthy enough to engage in sexual

activity. If you experience chest pain, nausea, or any other discomforts during sex, seek immediate medical help.

STENDRA may affect the way other medicines work. Tell your healthcare provider if you take any of the following: medicines called HIV protease inhibitors, such as ritonavir (Norvir®), indinavir (Crixivan®), saquinavir (Fortavase® or Invirase®) or atazanavir (Reyataz®); some types of oral antifungal medicines, such as ketoconazole (Nizoral®), and itraconazole (Sporanox®); or some types of antibiotics, such as clarithromycin (Biaxin®), telithromycin (Ketek®), or erythromycin.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including STENDRA) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including STENDRA, and call a doctor right away.

Sudden decrease or loss of hearing has been rarely reported in people taking PDE5 inhibitors, including STENDRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If you experience sudden decrease or loss of hearing, stop taking STENDRA and contact a doctor right away. If you have prostate problems or high blood pressure for which you take medicines called alpha blockers or other anti-hypertensives, your doctor may start you on a lower dose of STENDRA.

Drinking too much alcohol when taking STENDRA may lead to headache, dizziness, and lower blood pressure.

STENDRA in combination with other treatments for ED is not recommended.

STENDRA does not protect against sexually transmitted diseases, including HIV.

The most common side effects of STENDRA are headache, flushing, runny nose and congestion.

Please see full patient prescribing information for STENDRA (50 mg, 100 mg, 200 mg) tablets.

About VIVUS

VIVUS is a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. For more information about the company, please visit www.vivus.com.

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to regulatory approval of avanafil within the Sanofi territories; risks and uncertainties related to the timing and success of avanafil commercialization by Sanofi in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia; and risks and uncertainties related to the timing and success of avanafil commercialization by the Menarini Group and Auxilium Pharmaceuticals, Inc. in their respective territories. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS's Form 10-K for the year ending December 31, 2012, as amended by the Form 10-K/A filed on April 30, 2013, and as amended by the Form 10-K/A filed on June 12, 2013, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

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