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VIVUS, Inc. Announces License Agreement for the Marketing Rights to STENDRA in the United States and Canada

MOUNTAIN VIEW, Calif., Oct. 11, 2013 (GLOBE NEWSWIRE) -- VIVUS, Inc. (Nasdaq:VVUS) today announced the signing of an agreement providing Auxilium Pharmaceuticals, Inc. (Nasdaq:AUXL) the exclusive rights to market STENDRA™ (avanafil) in the United States and Canada. The parties also simultaneously signed a Commercial Supply Agreement pursuant to which VIVUS will be responsible for the manufacture and supply of STENDRA to Auxilium for a mutually agreed term. STENDRA is an oral therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of erectile dysfunction (ED). Under the license agreement, VIVUS is eligible to receive up to \$300 million based on certain regulatory and sales milestones, including an upfront licensing fee of \$30 million and a \$15 million payment contingent upon a potential label amendment regarding onset-of-action, in addition to royalties on product sales.

"Auxilium is the ideal partner for STENDRA, with an established sales force and excellent relationships with physicians responsible for men's health," stated Seth H.Z. Fischer, CEO of VIVUS. "We look forward to working with Auxilium as they prepare for launch later this year."

It is estimated that more than 50 percent of men over 40 years of age experience some degree of EDⁱ. Prevalence of the condition increases with age and can be caused by a variety of factors, including medications (anti-hypertensives, histamine receptor antagonists); lifestyle (tobacco, alcohol use); diseases (diabetes, cardiovascular conditions, prostate cancer); prostatectomy, and spinal cord injuries. The market opportunity for ED medical treatments continues to grow, with U.S. sales exceeding \$2.9 billion in 2012ⁱⁱ. About one half of men being treated with currently available PDE5 inhibitors are dissatisfied with the results of that treatment and tend to switch among the products in pursuit of better efficacy or less side effectsⁱⁱⁱ.

"We believe STENDRA complements our current portfolio of testosterone replacement therapy and ED products, further broadening our men's health care franchise in a very large market segment consisting of patients that tend to switch among products," said Adrian Adams, chief executive officer and president of Auxilium. "The rapid onset of action of STENDRA and its favorable side effect profile make it an exciting new entrant into the category."

Auxilium expects to begin its commercial launch of STENDRA by the end of 2013, first with shipments of STENDRA in December 2013, followed by promotional activities in early January 2014 with its PRIMERA sales force, which consists of 150 representatives currently devoted to strategic targeting of urologists, endocrinologists, and certain high prescribing primary care physicians. Auxilium will also leverage digital media to reach a broader audience online.

"The Agreement with Auxilium in the U.S. and Canada, along with the previously-announced license agreement with Menarini for Europe and abroad, fulfills significantly our objective of monetizing avanafil," stated Timothy E. Morris, senior vice president, finance and global commercial development, chief financial officer for VIVUS. "Both deals combined have the potential to generate over \$95 million in cash to VIVUS within the first year, in addition to royalties earned on sales of avanafil."

VIVUS will continue to be responsible for the product's post-approval requirements in the U.S., including a potential label amendment based on the results of the TA-501 study designed to assess the efficacy of STENDRA in approximately 15 minutes. In the study, STENDRA patients achieved statistically significant improvement over placebo, in the mean proportion of attempts that resulted in erections sufficient for successful intercourse, as early as 10 minutes for the 200 mg dose and 12 minutes for the 100 mg dose after being taken.

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

About Avanafil

STENDRA (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Auxilium Pharmaceuticals, Inc. has exclusive marketing rights to STENDRA in the U.S. and Canada.

STENDRA will be available through retail and mail order pharmacies. Auxilium plans to offer programs that will help patients with out-of-pocket costs.

SPEDRA, the trade name for avanafil in the EU, is approved by the EMA for the treatment of erectile dysfunction in the EU. 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.

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 is in discussions with other parties for the commercialization rights to 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 VIVUS, 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 certain avanafil claims within the Auxilium exclusive territories and the timing, strategy, tactics and success of avanafil commercialization by Auxilium in the U.S. or Canada. 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.

ⁱ The Massachusetts Male Aging Study

ⁱⁱ US TRx revenues per Symphony Health

ⁱⁱⁱ 1- Impact CR Consumer Segmentation, Feb 2013; Qualitative Market Interviews (n= 722)

2- HCP Research, Primary Interviews; LSSG, LLC n= 64

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