

# VIVUS and Metuchen Pharmaceuticals Announce License Agreement for Commercial Rights to STENDRA

## VIVUS Grants an Exclusive License to Metuchen Pharmaceuticals for STENDRA(R) (Avanafil) Commercial Rights in the U.S., Canada, South America and India

MOUNTAIN VIEW, CA and CRANFORD, NJ -- (Marketwired) -- 10/03/16 -- VIVUS, Inc. (NASDAQ: VVUS) ("VIVUS") and Metuchen Pharmaceuticals LLC ("Metuchen") today announced an agreement providing Metuchen a fully-paid, perpetual

license for exclusive rights to commercialize STENDRA<sup>®</sup> (avanafil) in the U.S., Canada, South America and India. The parties simultaneously signed a commercial supply agreement pursuant to which VIVUS will be responsible for the manufacture and supply of STENDRA to Metuchen for a mutually agreed term. For a period of 180 days, Metuchen has the option to assume the manufacturing and supply rights of STENDRA for its territories. Under the license agreement, VIVUS received \$70 million. Additionally, Metuchen will be responsible for royalties due to Mitsubishi Tanabe Pharma Corporation based on net sales.

STENDRA is an oral phosphodiesterase type 5 inhibitor. STENDRA was approved by the FDA in April 2012 for the treatment of erectile dysfunction in the United States and sold under the trade name SPEDRA in the European Union. VIVUS retains rights to receive royalties and milestones from the exclusive licenses to commercialize and promote SPEDRA with the Menarini Group in over 40 European countries plus Australia and New Zealand and with Sanofi in Africa, the Middle East, Turkey, and the Commonwealth of Independent States including Russia. Commercial rights remain available for Mexico and Central America.

"We are excited to announce our license agreement with Metuchen, who has commercial experience to take advantage of STENDRA's clinical profile within the erectile dysfunction market. This agreement is the first announcement to arise out of the strategic business review process announced earlier this year," stated Seth H. Z. Fischer, VIVUS CEO. "We are pleased to monetize our assets to maximize stockholder value and we look forward to providing additional updates on the on-going process."

### About Avanafil

STENDRA<sup>®</sup> (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Metuchen Pharmaceuticals LLC has exclusive marketing rights to STENDRA in the U.S., Canada, South America and India.

STENDRA is available through retail and mail order pharmacies.

SPEDRA<sup>™</sup>, 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.

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.

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

 ${\sf STENDRA}^{\circledR} \ (avanafil) \ is \ prescribed \ to \ treat \ erectile \ dysfunction \ ({\sf ED}).$ 

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<sup>®</sup>), indinavir (Crixivan<sup>®</sup>), saquinavir (Fortavase<sup>®</sup> or Invirase<sup>®</sup>) or atazanavir (Reyataz<sup>®</sup>); some types of oral antifungal medicines, such as ketoconazole (Nizoral<sup>®</sup>), and itraconazole (Sporanox<sup>®</sup>); or some types of antibiotics, such as clarithromycin (Biaxin<sup>®</sup>), telithromycin (Ketek<sup>®</sup>), 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 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 potential change in our business strategy to enhance long-term stockholder value; risks and uncertainties related to the timing, strategy, tactics and success of the commercialization of STENDRA (avanafil) by our sublicensee in the U.S., Canada, South America and India; risks and uncertainties related to our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with MTPC in which we do not have a commercial collaboration; and risks and uncertainties related to our ability to protect our intellectual property and litigation in which we are involved or may become involved. 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' Form 10-K for the year ended December 31, 2015 as filed on March 9, 2016 and as amended by the Form 10-K/A filed on April 22, 2016, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

#### **About Metuchen**

Metuchen Pharmaceuticals LLC is a privately-held specialty pharmaceutical company dedicated to improving men's health through innovative proprietary pharmaceutical products that have unique and meaningful clinical benefits.

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Source: VIVUS, Inc.

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