

March 27, 2017

## VIVUS, Inc. Reacquires STENDRA(R) (Avanafil) Commercial Rights from Sanofi

# VIVUS to Receive Commercial Rights to Africa, the Middle East, Turkey and the Commonwealth of Independent States, Including Russia

CAMPBELL, CA -- (Marketwired) -- 03/27/17 -- VIVUS, Inc. (NASDAQ: VVUS) (the "Company"), announced today that it reached an agreement with Sanofi to return the commercial rights for STENDRA in Africa, the Middle East, Turkey and the Commonwealth of Independent States, including Russia, to VIVUS. As part of the agreement, Sanofi will provide transition services to avoid adverse impacts to the regulatory approval applications in process, specifically in Russia and certain Middle East countries.

"The return of STENDRA from Sanofi provides us with the opportunity to find a commercial partner in the former Sanofi territories and continue our efforts to build long-term stockholder value," said Seth H. Z. Fischer, VIVUS Chief Executive Officer. "We have begun the process of finding a commercial partner to take advantage of Sanofi's efforts to obtain regulatory approvals in Russia and the Middle East. We look forward to continuing our relationship with Sanofi as the manufacturer of STENDRA."

### <u>About Avanafil</u>

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.

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 <u>www.STENDRA.com</u>.

### Important Safety Information

STENDRA<sup>®</sup> (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<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 developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health. For more information about the company, please visit <u>www.vivus.com</u>.

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 sublicensees in the U.S., Canada, South America, India, the EU, Australia and New Zealand; 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, including the former Sanofi territories; risks and uncertainties related to Sanofi Chimie's ability to undertake manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake manufacturing of the tablets for avanafil; risks and uncertainties related to our ability to manage the supply chain for STENDRA/SPEDRA for our collaborators; the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; risks related to the failure to obtain foreign authority clearances or approvals and noncompliance with foreign authority regulations; 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, 2016 as filed on March 8, 2017, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

VIVUS, Inc. Mark Oki Chief Financial Officer <u>oki@vivus.com</u> 650-934-5200

VIVUS Investor Relations: The Trout Group Brian Korb Managing Director <u>bkorb@troutgroup.com</u> 646-378-2923

Source: VIVUS, Inc.

News Provided by Acquire Media