Investor Relations - SWK Holdings

Acerus Files a New Drug Submission for Avanafil in Canada

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (TSX:ASP) (“Acerus” or the “Company”) today announced that it has filed a New Drug Submission (“NDS”) for Avanafil with Health Canada. Avanafil, a treatment for erectile dysfunction (“ED”), is a new, second generation PDE5 inhibitor, which has increased receptor specificity for fast onset of action and lower off-target side effects.

“The filing of the Avanafil NDS is an important next step in solidifying our presence in men’s health. If approved, Avanafil will become a key growth driver of our Canadian men’s health franchise and a strong complement alongside NATESTO®,” said Ed Gudaitis, President and Chief Executive Officer of Acerus. “We look forward to working with Health Canada to help bring this new treatment option to Canadians suffering from erectile dysfunction.

About Avanafil

The safety and efficacy of Avanafil is supported by four randomized, double-blind, placebo-controlled, parallel trials, which included subjects with erectile dysfunction from either a general ED population, ED patients with diabetes or ED patients following bilateral nerve-sparing radical prostatectomy. In all Phase 3 trials, statistically significant improvement in the primary efficacy measures were observed and were maintained throughout the 8-12-week treatment period. This included statistically significant improvements of +40% to +75% in the erectile function domain of the International Index of Erectile Function (IIEF). Avanafil treatment produced statistically significant increases in vaginal penetration (up to 77%, $p<0.01$) and successful intercourse (up to 57%, $p<0.01$). In a trial examining the time-to-onset, Avanafil significantly increased the proportion of subjects with successful intercourse as early as 15 minutes and at 6 hours.

Avanafil is available in the U.S. under the brand name STENDRA® (Avanafil) and is indicated for the treatment of erectile dysfunction. Metuchen Pharmaceuticals LLC (“Metuchen”) has exclusive marketing rights to STENDRA® in the U.S. Acerus licensed Avanafil from Metuchen for distribution in Canada.

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

Erectile Dysfunction Market in Canada

According to the Canadian study of Erectile Dysfunction, approximately 49% of men over 40 suffer from ED, a condition affecting their physical and psychosocial well-being and quality of life.[1]

The erectile dysfunction market is comprised of both maintenance and acute products. The acute products comprised 81.8% of yearly sales in 2017. In 2017, the erectile dysfunction market totaled CDN$231.9 million for prescription products, with a growth of 5.6% from the previous year.[2] Sales for the total erectile dysfunction products for six months ending June 2018 were CDN$166.9 million with a growth of 5.5% from the first six months in 2017.[2]

About Acerus

Acerus Pharmaceuticals Corporation is a Canadian-based specialty pharmaceutical company focused on the development, manufacture, marketing and distribution of innovative, branded products that improve patient experience, with a primary focus in the field of men’s and women’s health. The Company commercializes its products via its own salesforce in Canada, and through a global network of licensed distributors in the U.S. and other territories.

Acerus’ shares trade on TSX under the symbol ASP. For more information, visit www.aceruspharma.com and follow us on Twitter and LinkedIn.

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.

For more information, go to https://www.metuchenpharma.com.

Notice regarding forward-looking statements

Information in this press release that is not current or historical factual information may constitute forward-looking information within the meaning of securities laws. Implicit in this information are assumptions regarding our future operational results. These assumptions, although considered reasonable by the company at the time of preparation, may prove to be incorrect. Readers are cautioned that actual performance of the company is subject to a number of risks and uncertainties, including with respect to the likelihood of Avanafil being approved by Health Canada and, if so approved, the potential commercial success of Avanafil in Canada, and could differ materially from what is currently expected as set out above. For more exhaustive information on these risks and uncertainties you should refer to our annual information form dated March 20, 2018 that is available at www.sedar.com and the annual information form dated March 4, 2019 that will be available as of this evening on www.sedar.com. Forward-looking information contained in this press release is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time, whether as a result of new information, future events or otherwise, except as required by applicable securities laws.

[1] See 2015 CUA Practice Guidelines for Erectile Dysfunction as published in CAN UROL ASSOC J 2015; 9(1-2): 23-9

[2] IQVIA Canadian Drugstore and Hospital Audit (June 2018)

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Acerus Pharmaceuticals Corporation
Tricia Symmes
Chief Operating Officer
tsymmes@aceruspharma.com
(416) 509-2116
