

## Acerus Provides Update On Avanafil Health Canada Submission

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (TSX:ASP, OTCQB:ASPCF) ("Acerus" or the "Company") today announced that Health Canada has completed the initial screening process for the previously announced New Drug Submission ("NDS") for avanafil. The dossier is now in active review by Health Canada and Acerus expects review completion and, if approved, Notice of Compliance issuance to be in early Q2 of 2020.

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.

"We are pleased to report that avanafil is under active review by Health Canada. If approved, avanafil will become a key growth driver of our Canadian men's health franchise alongside NATESTO<sup>®</sup>," said Ed Gudaitis, President and Chief Executive Officer of Acerus. "The product is complementary to the current call point of our Canadian sales team and will allow Acerus to leverage our commercial investment in Canada.

### 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<sup>®</sup> (avanafil) and is indicated for the treatment of erectile dysfunction. Metuchen Pharmaceuticals LLC ("Metuchen") has exclusive marketing rights to STENDRA<sup>®</sup> in the U.S. Acerus licensed avanafil from Metuchen for distribution in Canada.

For more information about STENDRA<sup>®</sup>, please visit [www.STENDRA.com](http://www.STENDRA.com).

### About Acerus

Acerus Pharmaceuticals Corporation is a Canadian-based specialty pharmaceutical company focused on the commercialization and development of innovative prescription products that improve patient experience, with a primary focus in the field of men'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 and on OTCQB under the symbol ASPCF. For more information, visit [www.aceruspharma.com](http://www.aceruspharma.com) and follow us on [Twitter](#) and [LinkedIn](#).

### 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 4, 2019 that will be available as of this evening on [www.sedar.com](http://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.

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