

## **Acerus Announces Publication of Study Results Demonstrating Effectiveness of NATESTO® Regardless of Baseline Symptom Severity**

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (TSX: ASP, OTCQB: ASPCF) ("Acerus" or the "Company") announced today the acceptance of a new manuscript to the Journal of the Endocrine Society, describing how NATESTO® achieves similar symptom improvement, regardless of the degree of a patient's baseline testosterone deficiency.

"Acerus continues to achieve important scientific milestones related to the global evolution of NATESTO®. With the publication of the study entitled Efficacy of Nasal Testosterone Gel (NATESTO®) Stratified by Baseline Endogenous Testosterone Levels, we now have evidence that the product is effective in patients regardless of the degree of their baseline hypogonadism," said Ed Gudaitis, President and Chief Executive Officer of Acerus Pharmaceuticals.

This new scientific report describes a post-hoc analysis of data from the pivotal Phase 3 study of NATESTO®, which enrolled 306 patients from 52 sites in the United States, who were treated with NATESTO® for up to 1 year. Patient data from the phase 3 study was classified based on the degree of testosterone deficiency demonstrated by patients at study entry. Each dose of NATESTO® resulted in a short-term return of testosterone to the upper normal range (800 ng/dL; 28 nmol/L) irrespective of how low the patient's baseline testosterone was prior to the study. In the patient group with the lowest baseline testosterone level, a mean average serum testosterone level of 295 ng/dL (10.2 ng/dL) was achieved with NATESTO® exposure. As well, statistically significant improvements in symptom relief (erectile function, mood and lean body mass) were observed in these patients. In between NATESTO® doses, all patients in the phase 3 study maintained their natural testosterone at the same levels they had prior to entry into the study, indicating that NATESTO® does not suppress natural testosterone production. Based on the data, Acerus believes that the mechanism of action of NATESTO® is unique whereby the peaks in testosterone generated by NATESTO® dosing provide efficacy and improvement of symptoms, while the time between doses (4-8 hours) allows for the maintenance of testicular testosterone production and sperm production.

"The pharmacology of NATESTO® is unique from other testosterone products that treat low testosterone or hypogonadism", said Dr. Ethan Grober, Associate Professor, Division of Urology, University of Toronto and one of the new study's authors. "The release of testosterone with NATESTO® is pulsatile - closely matching the bodies "natural" testosterone release. Consequently, NATESTO® does not suppress a man's natural testosterone level, but simply adds to it to achieve a normal, safe level of testosterone. Furthermore, NATESTO® has been shown to work even in severely testosterone deficient patients, suggesting that a wide range of testosterone deficient patients can be effectively treated".

### **About NATESTO® (Testosterone) Nasal Gel**

NATESTO® is a nasal gel formulation of testosterone developed by Acerus Pharmaceutical Corporation and indicated as a replacement therapy for men diagnosed with conditions associated with a deficiency or absence of endogenous testosterone (hypogonadism). It is the first and only nasally-administered testosterone product approved by the U.S. FDA, Health Canada and South Korea and available in a 'no-touch' dispenser with a metered dose pump. A copy of the NATESTO® Canadian product monograph can be found at: <http://www.aceruspharma.com/English/products-and-pipeline/NATESTO®/default.aspx>. For further information, specific to the U.S. product dosing and administration, please visit: [www.NATESTO®.com](http://www.NATESTO®.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 commercial performance of NATESTO<sup>®</sup>, 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 which is available at [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 law.

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<https://swkhold.investorroom.com/2019-07-08-Acerus-Announces-Publication-of-Study-Results-Demonstrating-Effectiveness-of-NATESTO-R-Regardless-of-Baseline-Symptom-Severity>