

Acerus Provides Update on Temporary Unavailability of NATESTO® in Canada and South Korea

Current NATESTO® supply to the United States remains unaffected

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (TSX:ASP, OTCQB:ASPCF) today provided an update on the temporary unavailability of NATESTO® in Canada and South Korea, following the previous announcement of the voluntary replacement of certain NATESTO® lots released on the Canadian and South Korean markets.

Acerus made minor modifications to the manufacturing process that appear to have resolved the previously identified issues and has produced a batch of NATESTO® (the “Revised Batch”). While Acerus believed the changes would have been classified by Health Canada as level III, thereby requiring only an annual notification update to Health Canada and allowing for product to be released in Q4-2019, Health Canada, after much deliberation, classified the modifications as level I, requiring the submission of a Supplemental New Drug Submission (“SNDS”) prior to the release of the Revised Batch in the Canadian market. In the event that Health Canada utilizes the full regulatory allotted time for reviewing a SNDS, Acerus would expect the Revised Batch to be released in the Canadian Market in Q1-2021. Acerus continues to work with Health Canada to facilitate an expeditious review of the SNDS and minimize market disruptions.

At this time, the current supply of NATESTO® to the United States is not affected by this situation. Acerus is working with its South Korean partner to determine whether the Revised Batch can be released in the South Korean market and, if so, under what timeframes.

About NATESTO® (Testosterone) Nasal Gel

NATESTO® is a nasal gel formulation of testosterone developed by Acerus Pharmaceuticals 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. Food and Drug Administration, Health Canada and South Korea Ministry of Food and Drug Safety (MFDS), available in a ‘no-touch’ dispenser with a metered dose pump. A copy of the NATESTO® Canadian product monograph can be found at: http://s2.q4cdn.com/417379002/files/doc_downloads/NATESTO-PM-APR-2019-EN.pdf. For further information, specific to the U.S. product dosing and administration, please visit: 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 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 duration of the NATESTO® shortage in Canada and South Korea, 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. 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20191101005061/en/): <https://www.businesswire.com/news/home/20191101005061/en/>

Edward Gudaitis
President and Chief Executive Officer
egudaitis@aceruspharma.com
(905) 817-8194

<https://swkhold.investorroom.com/2019-11-01-Acerus-Provides-Update-on-Temporary-Unavailability-of-NATESTO-R-in-Canada-and-South-Korea>