Acerus Provides Business Update on NATESTO®

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (TSX:ASP) (“Acerus” or the “Company”) announced today two updates relative to the Company’s NATESTO® business. First, the Company announced making the first shipment of NATESTO® to South Korea. Second, the Company announced 2 new, peer-reviewed publications describing results from the NATESTO® My-T study.

Hyundai Pharm Co., Ltd. (“Hyundai”), Acerus’ licensee for South Korea, has confirmed receipt of its first purchase order of NATESTO® destined for the South Korean market and has placed a second purchase order for delivery in Q2-2019. Hyundai has also informed Acerus that it intends to launch NATESTO® at the end of Q1 or beginning of Q2 of 2019. This marks the first commercial launch of NATESTO® outside North America.

“Acerus has reached an important milestone, with South Korea being the third region globally to commercialize NATESTO®. We look forward to the success of Hyundai’s launch and to continuing the global expansion of NATESTO®. As well, with the publication of the My-T study, we now have evidence that experienced testosterone users may actually prefer NATESTO® versus other testosterone therapies,” said Ed Gudaitis, President and Chief Executive Officer of Acerus Pharmaceuticals.

The two new scientific reports related to NATESTO® were published in the online version of the Canadian Urological Association Journal and describe the My-T Study (the “Study”), a multicenter, open-labeled clinical trial to assess treatment safety and efficacy of NATESTO® as well as patient preference for subjects switched from a prior topical medication to the nasal product. Part 1, published electronically on 2019 February 12 (https://cuaj.ca/index.php/journal/article/view/5662) is entitled “My-T Study: Symptom-based titration decisions when using testosterone nasal gel, NATESTO®” and Part 2 published electronically on 2019 February 26 (https://cuaj.ca/index.php/journal/article/view/5680) is entitled “My-T study: Patient satisfaction and preference comparing topical and nasal testosterone therapies.”

The Study enrolled 117 hypogonadal males, 75% of whom were on a topical TRT prior to study initiation. The Study assessed a titration methodology based on improvement in patient symptoms, a key treatment outcome according to Canadian Men’s Health Foundation Multidisciplinary Guidelines and as endorsed by both the Canadian Urological Association and the Canadian Society of Endocrinology and Metabolism. Titration outcomes were confirmed by analysis of serum total testosterone levels. The Study captured information on symptoms and patient treatment satisfaction prior to, as well as after, NATESTO® treatment in order to glean information on NATESTO® relative to their prior topical medication. The Study found that titration based on symptoms was successful in achieving normal levels of total testosterone in 77% of patients with statistically significant improvements in symptoms. The symptoms predictive of success were erectile function, libido and energy/endurance. Patients switched from topical therapy to NATESTO® also reported significant improvements in clinical symptoms of hypogonadism ($p<0.0001$; +15%), increased treatment effectiveness (+20%), convenience (+30%) and global satisfaction (+3%) compared to their previous topical TRT. The Study clearly showed that patients perceived NATESTO’s® fast, easy nasal dosing schedule as a convenience when compared to once-daily topical products spread by hand over the shoulders and thighs. Overall, 67.2% of patients agreed or strongly agreed that they preferred testosterone nasal gel over topical TRT, citing ease of use, convenience, effectiveness and travel friendliness as advantages of the nasal therapy.

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.

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 Hyundai Pharm Co., Ltd.

Founded in 1965, HYUNDAI Pharm Co., Ltd. is a pharmaceutical company engaged in R&D, manufacturing and distribution of pharmaceutical products, health and food drinks, as well as medical equipment. In the pharmaceutical field, HYUNDAI is a leading expert in various therapeutic categories (CV, respiratory system, women's & men's health, CNS, and oncology) with specialized and unique products. The company is head quartered in Seoul, South Korea and is publicly traded on the Korea Stock Exchange. For more information, visit www.hyundaipharm.co.kr/english/index.jsp.

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 potential commercial success of NATESTO® in Korea and the impact of the My-T Study might have on the commercial success of NATESTO®, 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 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.

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