New Data Demonstrates That NATESTO® Increases Serum Testosterone and Improves Symptoms While Maintaining Normal Semen Parameters in Men With Low Testosterone Through Six Months

NATESTO ® shown to significantly increase mean testosterone levels, while maintaining sufficient gonadotropins to preserve fertility
Improvement in quality-of-life, overall satisfaction and sexual desire was reported
Approximately 65% of men become infertile when prescribed other testosterone therapies for six months; recovery is not assured following discontinuation of these therapies1,2

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (TSX:ASP, OTCQB:ASPCF) today announced the presentation of data from the NATESTO® Spermatogenesis Study as part of the "Late Breaking" Abstract Session at the 75th Annual American Society for Reproductive Medicine (ASRM) Scientific Conference in Philadelphia, PA. Yesterday's presentation was one of only six abstracts accepted as part of this session.

Findings from the study demonstrated that 95% of men treated with NATESTO® for hypogonadism for three and six months, maintained their semen parameters within the normal range while increasing serum testosterone levels to normal and improving hypogonadal symptoms. This is the first such study to demonstrate conclusively that a testosterone replacement therapy (TRT) can maintain key fertility parameters in hypogonadal men. Researchers attributed these findings to NATESTO®'s fast absorption and unique dosing schedule designed to produce fluctuations of testosterone levels in the bloodstream.

"Low testosterone affects about 12% of men under 40, at a time when their interest in having a family may be highest. Unfortunately, the therapies we use to restore testosterone levels can impact sperm production and function, resulting in infertility," said Ranjith Ramasamy, MD, Associate Professor and Director of Reproductive Urology at the University of Miami School of Medicine and the study's principal investigator. "Our study shows that NATESTO® can be a good option for these men. After six months of treatment, the majority of patients in our study were able to maintain normal levels of sperm production and quality. Any patient with a modest decrease in sperm parameters returned to their pre-study sperm levels within three months of stopping treatment, something we don't often see with other testosterone replacement therapies."

The Phase IV, single-site, prospective study evaluated hypogonadal men, ages 18 to 55, who completed up to a six-month treatment period with NATESTO®. The primary endpoints examined:

- Hormones, including testosterone, hydroxyprogesterone (a marker of endogenous testosterone production), luteinizing hormone (LH) and follicle stimulating hormone (FSH) at three and six months;
- Sperm parameters, including sperm concentration, motility, and total motile sperm count at three and six months; and
- Symptoms of low testosterone as measured by the SF-36, and the International Index of Erectile Dysfunction (IIEE) at three and six months.

Key Study Findings:

In total, 55 men were eligible and enrolled in the trial. Of the 55 who enrolled, 33 patients have completed the six-month treatment period.

Nearly all subjects completing the six-month treatment period had their testosterone levels return to the normal range. Mean (SD) serum testosterone levels increased from 230 (62) ng/dL at baseline to 605 (278) ng/dL at six months (p=0.005). In addition, mean baseline levels of Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) (3.9 IU/mL and 4.0 IU/mL, respectively) were preserved within the normal range over this time (2.6 IU/mL and 3.0 IU/mL, respectively).

Most importantly, mean semen parameters remained unchanged (P > 0.05):

Semen Parameter	Baseline (SD)	3 Months, n= 44 (SD)	6 Months, n=33 (SD)
Sperm Concentration (million/cc)	31.9 (21.8)	26.2 (19.6)	24.5 (15.8)
Sperm Motility (%)	52.6% (12.0)	50.2% (19.2)	51.6% (15.2)
Total Motile Sperm Count (million)	47.1 (46.1)	42.4 (61.4)	34.1 (24.1)

Additionally, there was improvement across all domains of erectile function including libido and overall sexual satisfaction, as well as improvement in overall energy, which are common hypogonadal symptoms.

No serious adverse events (AEs) were reported in the study. The most commons AEs were nasal irritation (five cases, 13.1%), oligospermia (three cases, 7.9%) and azoospermia (one case, 2.6%). All of these men recovered spermatogenesis after discontinuation.

"For the first time, a testosterone replacement therapy has been proven to increase serum testosterone while actually maintaining sperm concentration, motility, and total motile sperm count," said Ed Gudaitis, President and Chief Executive Officer of Acerus. "This clearly differentiates NATESTO® from other approved testosterone therapies. We're very excited by the outcomes of this study and will look to further develop the growing evidence-base supporting NATESTO®."

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. 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://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.

IMPORTANT SAFETY INFORMATION

NATESTO® is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone (hypogonadism).

Contraindications: Men with known or suspected carcinoma of the prostate or breast; women; pregnant and nursing women should avoid skin contact with NATESTO®; men with known hypersensitivity to any of its ingredients.

Other relevant warnings and precautions: Nasal adverse reactions, including nasopharyngitis, rhinorrhea, epistaxis, nasal discomfort and nasal scabbing; use with caution in patients with pre-existing cardiovascular (e.g., congestive heart failure, ischemic heart disease), renal, or hepatic disease; nasal disorders; nasal or sinus surgery; nasal fracture within previous 6 months or deviated anterior nasal septum; mucosal inflammatory disorders; and sinus disease; should not be used to improve body composition, bone and muscle mass, increase lean body mass, decrease total fat mass, enhancement of athletic performance, nor for the treatment of male infertility or sexual dysfunction if testosterone deficiency has not been established; schedule G controlled substance; must monitor the occurrence of prostatic hyperplasia, prostate cancer and breast cancer. verify the existence of a pre-existing prostate cancer before starting treatment with testosterone replacement; in patients with skeletal metastases, regular monitoring of serum calcium concentrations is recommended; use with caution in patients with hypertension; in patients suffering from severe cardiac, hepatic, or renal insufficiency or ischaemic heart disease, treatment with testosterone may cause serious complications characterized by edema, with or without congestive cardiac failure, and in such cases, treatment must be stopped immediately; myocardial infarction, stroke, and venous thromboembolic events (deep vein thrombosis, pulmonary embolism): if these events are suspected, treatment with NATESTO® should be discontinued and appropriate assessment and management should be initiated; assess cardiovascular risk before starting treatment with testosterone replacement; diabetics should be followed carefully and the insulin or oral hypoglycemic dosage adjusted accordingly; hypercalciuria/hypercalcemia may be exacerbated by androgen treatment; may be necessary to reduce the dose of oral anticoagulants in patients who take them; treatment may potentiate sleep apnea; the patient may develop gynecomastia (1 to 3%), priapism or oligospermia; laboratory tests, performed routinely, are recommended: testosterone, hemoglobin and hematocrit, liver function tests, PSA, digital rectal examination, lipid profile, breast exam, international normalized ratio (INR) and prothrombin time in patients taking anticoagulants." Consult the Product Monograph at: http://s2.q4cdn.com/417379002/files/doc_downloads/NATESTO-PM-EN.pdf for more information about conditions of clinical use, contraindications, warnings, precautions, adverse reactions, interactions and dosing.

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, through a pending joint third-party and co-promotion partnership in the U.S. and through a global network of licensed distributors in 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 commercial performance of NATESTO® and the impact of the Spermatogenesis study on such performance, 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.

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[1] World Health Organization Task Force on methods for the regulation of male fertility. Lancet. 1990

[2] Liu et al. Lancet. 2006

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