Acerus Announces Publication of Results for NATESTO® Spermatogenesis Study in Journal of Urology

NATESTO® Increases Serum Testosterone and Improves Hypogonadal Symptoms While Preserving Sperm Parameters Within Normal Range

Toronto, Canada, April 21, 2020 – Acerus Pharmaceuticals Corporation (TSX:ASP, OTCQB:ASPCF) ("Acerus" or the "Company") today announced the acceptance of the NATESTO® Spermatogenesis Study results for publication in an upcoming issue of the Journal of Urology.

The single-institution, open-label, single-arm trial was conducted between November 2017 and September 2019 at the University of Miami's Department of Urology. The study concluded that NATESTO® was found to be both effective in restoring hypogonadal men to normal testosterone levels, while also simultaneously improving both erectile function and quality of life. Importantly, gonadotropin hormones remained within normal ranges and semen parameters were preserved through 6 months of treatment in 95% of men.

"Testosterone therapy is typically considered as a contraceptive and contraindicated in men interested in fertility. However, results from our clinical trial present a paradigm shift in the treatment of men with testosterone deficiency. The short-acting property of NATESTO® likely preserves gonadotropins and sperm parameters as compared to other commonly used testosterone therapies that are typically long-acting," said the study's principal investigator Dr. Ranjith Ramasamy, MD, Associate Professor and Director of Reproductive Urology at the University of Miami School of Medicine.

The study authors estimate that up to 16% of men being prescribed testosterone therapy (TTh) are under 39 years old. The most commonly prescribed testosterone therapies, injections and topical gels, can impair semen parameters and can cause azoospermia (absence of sperm in the semen) in up to 2/3^{rds} of men. Therapies such as clomiphene citrate, a selective estrogen receptor modulator (SERM), are widely used off-label to preserve spermatogenesis while simultaneously increasing testosterone. Many of these off-label products can have several adverse reactions; therefore, identifying alternatives to increase testosterone in men without impacting gonadotropin levels and sperm parameters is paramount.

The Phase IV clinical trial investigating the impact of nasally administered NATESTO® on restoration of testosterone and preservation of fertility parameters evaluated 44 subjects through 3 months, and 33 subjects through 6 months of treatment. Mean testosterone increased from 231 ng/dL to 652 ng/dL after 6 months of NATESTO® treatment. There was improvement across all domains of erectile function

(based in IIEF-15), with particularly significant improvements in sexual desire and overall satisfaction. Additionally, sperm concentration, sperm motility, and total motile sperm count were maintained through 6 months of NATESTO® treatment. Key data are summarized in the following table.

	Mean Values (SD)			
	Baseline	**3 Months**	**6 months**	**P value**
Testosterone (ng / dL)	231 (61)	616 (267)	652 (305)	< 0.001
	Semen Parameters			
Sperm Concentration (Mill. / cc)	29.9 (18.7)	25.9 (19.5)	24.2 (15.7)	> 0.05
Sperm Motility (%)	52.1 (12.3)	49.1 (20.4)	51.6 (15.2)	> 0.05
Total Motile Sperm Count (Mill.)	45.9 (45.5)	40.8 (60.5)	33.9 (24.3)	> 0.05
	Symptom Improvement			
IIEF - Sexual Desire	5.8 (2.2)	7.6 (1.3)	7.3 (1.6)	< 0.001
IIEF - Overall Satisfaction	6.0 (2.8)	7.8 (2.0)	7.8 (2.1)	0.001

"We now have clinical evidence demonstrating that a testosterone therapy has been proven to restore serum testosterone levels while maintaining gonadotropin hormones within the normal range, while also maintaining sperm concentration, motility, and total motile sperm count", said Ed Gudaitis, President and Chief Executive Officer of Acerus. "This clearly distinguishes NATESTO® from all other testosterone replacement therapies and can create a clinical paradigm shift across the spectrum of male reproductive health. Publication of the study in a high impact journal like the Journal of Urology indicates the clinical significance of these findings."

Acerus will evaluate options with respect to NATESTO® product labeling claims as it relates specifically to these study results and data.

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 the United States and Canada, 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 impact of the spermatogenesis study on the commercial potential of NATESTO®, and could differ materially from what is currently expected as set out above. In particular, these assumptions include but are not limited to, the following: the COVID-19 pandemic will not affect our business plan and that of our suppliers, the COVID-19 pandemic will not last many months and health care professionals will be available to hear about our products and to continue education programs related to them. For more exhaustive information on these risks and uncertainties you should refer to our annual information form dated March 3, 2020 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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