Aytu BioScience Announces Publication of Results from Natesto Spermatogenesis Study in Journal of Urology

Nasally-Administered Natesto Testosterone Replacement Therapy Increases Serum Testosterone, Improves Hypogonadal Symptoms While Simultaneously Preserving Semen Parameters and Gonadotropin Hormones

ENGLEWOOD, CO / April 21, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU) (the "Company"), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, announced the acceptance and publication of the Natesto® Spermatogenesis Study results into the *Journal of Urology* earlier this week.

The Phase IV single institution, prospective, clinical trial was conducted between November 2017 and September 2019 at the University of Miami's Department of Urology by lead author and the study's principal investigator Dr. Ranjith Ramasamy, MD, the Director of Reproductive Urology. The study concluded that Natesto was effective in returning hypogonadal men to back to normal testosterone levels, significantly improve erectile function and quality of life, preserve gonadotropin hormones, and most importantly preserve semen parameters through 6 months of treatment.

Studies estimate ~12.4 – 15.6% of men under 39 years old receive prescribed testosterone therapy (TTh). The most commonly prescribed testosterone therapies, injections and topical gels, can impair semen parameters and can cause azoospermia in up to 65% of men. Additionally, off-label use of therapies such as selective estrogen receptor modulators (SERMs) are widely used to preserve spermatogenesis while simultaneously increasing testosterone. Many of these off-label products can have numerous additional adverse reactions, therefore identifying alternatives to increase testosterone in men without impacting fertility is paramount.

The authors note, Natesto differs substantially in its short duration of action and frequency of administration, compared to other long-acting testosterone injections, gels, and pellets. They hypothesized that short-acting Natesto would have less suppressive effects on the hypothalamic-pituitary-gonadal (HPG) axis, and therefore lead to less suppression of spermatogenesis.

"The results from this clinical trial are encouraging – Natesto can be a safe and effective treatment option for men who wish to preserve fertility and sperm production," said the study's principal investigator Dr. Ranjith Ramasamy, Associate Professor and Director of Reproductive Urology at the University of Miami School of Medicine.

The Phase IV clinical trial investigating the impact of nasally-administered Natesto on 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.

	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

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, “The investigators, led by Dr. Ramasamy, clearly conclude from this study that hypogonadal men treated with Natesto are able to maintain their fertility as evidenced by the study participants’ maintenance of key semen parameters. For the first time, a testosterone replacement therapy has been shown to increase serum testosterone while actually maintaining sperm concentration, motility, and total motile sperm count. This distinguishes Natesto from all other testosterone replacement therapies and can create a clinical paradigm shift across the spectrum of male reproductive health. With these data now published, we believe Natesto will be primed for broader use and may present a more appropriate treatment for men with Low T who are still in their family formation years.”

Aytu BioScience’s Natesto co-promotion partner Acerus will evaluate options with respect to Natesto product labeling claims as it relates specifically to these study results and data.

About Aytu BioScience, Inc.

Aytu BioScience, Inc. is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. The Company currently markets a portfolio of prescription products addressing large primary care and pediatric markets. The primary care portfolio includes (i) Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”), (ii) ZolpiMist™, the only FDA-approved oral spray prescription sleep aid, and (iii) Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. The pediatric portfolio includes (i) AcipHex® Sprinkle™, a granule formulation of rabeprazole sodium, a commonly prescribed proton pump inhibitor; (ii) Cefaclor, a second-generation cephalosporin antibiotic suspension; (iii) Karbinal® ER, an extended-release carbinoxamine (antihistamine)

suspension indicated to treat numerous allergic conditions; and (iv) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various for infants and children with fluoride deficiency. Aytu recently acquired exclusive U.S. distribution rights to the COVID-19 IgG/IgM Rapid Test. This coronavirus test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 126 patient clinical trial in China and has received CE marking.

Aytu recently acquired Innovus Pharmaceuticals, a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve men's and women's health and vitality. Innovus commercializes over thirty-five consumer health products competing in large healthcare categories including diabetes, men's health, sexual wellness and respiratory health. The Innovus product portfolio is commercialized through direct-to-consumer marketing channels utilizing the Company's proprietary Beyond Human® marketing and sales platform.

Aytu's strategy is to continue building its portfolio of revenue-generating products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information visit aytubio.com and visit innovuspharma.com to learn about the Company's consumer healthcare products.

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this presentation, are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as 'may,' 'will,' 'should,' 'forecast,' 'could,' 'expect,' 'suggest,' 'believe,' 'estimate,' 'continue,' 'anticipate,' 'intend,' 'plan,' or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: our ability to successfully commercialize Healight Platform Technology, our ability to obtain FDA approval for the Healight Platform Technology, the effectiveness of the Healight Platform Technology in treating patients with COVID-19 or other illnesses, our ability to adequately protect the intellectual property associated with the Healight Platform Technology, regulatory delays, the reliability of the Healight Platform Technology in killing viruses and bacteria, market acceptance of UV based medical devices, risks associated with the COVID-19 Rapid Test including our ability to enforce the exclusivity provisions of the distribution agreement, the reliability of serological testing in detecting COVID-19, shipping delays and their impact on our ability to introduce

the COVID-19 Rapid Test, the ability of the COVID-19 Rapid Test to accurately and reliably test for COVID-19, the manufacturer of the COVID-19 Rapid Test's ability to manufacture such testing kits on a high volume scale, manufacturing problems or delays related to the COVID-19 Rapid Test, our ability to satisfy any labelling conditions or other FDA or other regulatory conditions to sell the COVID-19 Rapid Test Kit, the demand or lack thereof for the COVID-19 Rapid Test Kit, our ability to obtain additional COVID-19 Rapid Tests to meet demand, our ability to secure additional tests if the manufacture of the COVID-19 Rapid Tests is unable to meet demand, the effects of the business combination of Aytu and the Commercial Portfolio and the recently completed merger ("Merger") with Innovus Pharmaceuticals, including the combined company's future financial condition, results of operations, strategy and plans, the ability of the combined company to realize anticipated synergies in the timeframe expected or at all, changes in capital markets and the ability of the combined company to finance operations in the manner expected, the diversion of management time on Merger-related issues and integration of the Commercial Portfolio, the ultimate timing, outcome and results of integrating the operations the Commercial Portfolio and Innovus with Aytu's existing operations, risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors for our prescription products, the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future regulatory submissions and events, our anticipated future cash position and future events under our current and potential future collaboration. We also refer you to the risks described in 'Risk Factors' in Part I, Item 1A of the company's Annual Report on Form 10-K and in the other reports and documents we file with the Securities and Exchange Commission from time to time.

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