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3 Year Evaluation Confirms Long Term Safety and Effectiveness of Renessa® Procedure for Female Stress Urinary Incontinence

Non-surgical in-office treatment provides a new option for women

NEWARK, CALIF., November 7, 2006 – Novasys Medical, Inc., a developer of innovative therapies in women’s health, announced today that Saad Juma, M.D., of the Incontinence Research Foundation in Encinitas, California, presented the results of a study on the long term safety and effectiveness of the company’s Renessa® procedure for the treatment of stress urinary incontinence (SUI) in women. The study was presented at the Global Congress of Minimally Invasive Gynecology sponsored by the American Association of Gynecologic Laparoscopists (AAGL) in Las Vegas, Nevada. Dr. Juma reported that long term clinical outcomes showed a durable response to the Renessa treatment and confirmed an improvement in quality of life and a reduction in the frequency and severity of incontinence episodes in the majority of women almost 4 years after treatment.

The retrospective analysis evaluated the clinical results of women from a randomized controlled multicenter U.S. clinical trial that took place in 2002. Patient follow-up averaged 44 months following the Renessa procedure. Based on 3 day diaries and incontinence quality of life (I-QOL) surveys, 81% of women had no additional treatments for SUI and experienced a mean I-QOL improvement that was clinically significant. 56% of the women had more than a 50% reduction in the frequency of their incontinence episodes, the same as at one year. Satisfaction with the treatment and willingness to refer friends to the procedure remained high. There were no adverse events reported during the additional 2 year follow-up period.

“We are very pleased with the long term clinical outcomes of our Renessa treatment,” said Debra Reisenhel, President and Chief Executive Officer of Novasys Medical. “Durability of clinical results is critical to patients, their physicians, and health care payers. We are especially gratified knowing that this procedure offers a safe and straightforward alternative for women who seek a non-surgical solution for their incontinence.”

Rodney Appell, M.D., Professor of Urology at Baylor College of Medicine was the Principal Investigator for the original 12 month trial and the subsequent 3 year follow-up. “The Renessa treatment represents a promising alternative for women with SUI who are not good surgical candidates, or who may not desire an invasive procedure. The long term data suggest that the procedure maintains its safety and effectiveness for at least 3 to 4 years.”

SUI is the involuntary leakage of urine associated with laughing, coughing, sneezing, sexual and recreational activities. The condition is caused by a variety of factors, most commonly

childbirth, and often restricts the social, professional, and personal lives of an estimated 15 million women in the U.S. alone. With currently available surgical and non-surgical SUI therapies, many patients and physicians have concerns about safety, recovery, compliance, and/or effectiveness. In fact, it is estimated that approximately 80% of women with SUI do not seek treatment of any kind due to concerns over recovery time, possible complications or lack of confidence in the effectiveness of available options. The Renessa procedure offers women a new non-surgical approach to the effective treatment of SUI.

Women who participated in the long term evaluation were part of a prospective sham-controlled clinical study involving more than 170 women at 10 sites throughout the U.S. Key 12 month clinical outcomes for the 110 treated women in the study included:

- Statistically significant improvement in Valsalva Leak Point Pressure;
- 76% of women experienced a reduction in daily incontinence episodes;
- 58% of women no longer used incontinence pads;
- 67% of women reported an improvement in their quality of life; and
- 56% of women had a greater than 50% reduction in episodes.

The FDA-cleared Renessa System includes a small probe which a physician passes through the natural opening of the urethra (transurethral). The probe heats multiple small treatment sites in the submucosa of the bladder neck and upper urethra, denaturing collagen in the tissue. Upon healing, the treated tissue is less compliant, resulting in increased resistance to involuntary leakage at times of abdominal pressure, such as laughing, coughing or during exercise, thereby reducing or eliminating leaks.

The Renessa treatment can be performed in the convenience of a physician's office using local anesthesia. There are no incisions, bandages or dressings required. Recovery is rapid and comfortable, with minimal post-procedure limitations.

About Novasys Medical

Novasys Medical, Inc. is a privately held, venture-backed company which develops innovative therapies in women's health. The company's initial focus is the development and commercialization of the Renessa System, a proprietary, non-surgical approach to the treatment of female stress urinary incontinence (SUI).

For more information, please visit www.novasysmedical.com or call (510) 226-4060.

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