

Men with Low Testosterone See Multiple Doctors Before Being Diagnosed; Many Dissatisfied with Current Treatment Options

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New Long-Acting Injection in Development

WASHINGTON and CHADDS FORD, Pa., June 10 /PRNewswire/ -- About 63 percent of men who suffered from low testosterone saw two or more doctors before the condition was diagnosed, and once treated, nearly 30 percent of men said they stopped taking their medicine, according to results of a survey released today.

Results of the poll of more than 100 men who had been diagnosed with and treated for low testosterone, were released at the annual meeting of the Endocrine Society. The most frequent symptoms respondents reported were lack of energy (87 percent), decreased concentration (83 percent), loss of sex drive (82 percent) and the inability to get or maintain an erection (80 percent).

An estimated 13.9 million American men have low testosterone, also known as hypogonadism, yet only 9 percent of men are currently being treated with testosterone replacement therapy. The condition takes a significant toll on men's lives. Among men polled, 97 percent said low testosterone had a somewhat or very negative impact on the sexual aspect of their lives, and 90 percent said it adversely affected their self esteem.

"Low testosterone levels may have a marked impact on a man's sense of well being," said Raymond Rosen, Ph.D., Chief Scientist of the New England Research Institutes in Watertown, Mass. Among men polled, 61 percent said they were generally unsatisfied with their lives before being treated.

Low testosterone is associated with a broad range of physical, psychological and sexual symptoms including decreased energy and mood, fatigue, loss of muscle mass, depressed libido and erectile dysfunction. In addition, low testosterone has been associated with other serious medical conditions including diabetes, cardiovascular disease and metabolic syndrome.

"These symptoms are vague and non-specific, which may account for the apparent under-diagnosis of low testosterone," Dr. Martin M. Miner, MD , Co-Director of the Men's Health Center Miriam Hospital and Clinical, Providence, R.I. and Associate Clinical Professor of Family Medicine Warren Alpert School of Medicine of Brown University, said. According to the survey, 36 percent of respondents saw two physicians before being diagnosed while 19 percent saw three doctors and 9 percent saw four. "This clearly speaks to the need for greater awareness among physicians of the condition and also for more patient-friendly treatments, since most men with this hormone deficiency will need to stay on treatment for life," Dr. Miner said.

Current treatment options include transdermal patches and gels that must be applied to the skin on a daily basis. Patients using gels must take care to prevent any transfer of testosterone to partners or children, as they have been associated with inappropriate genitalia enlargement and aggression in children. Short-acting testosterone injections are another, less popular treatment option that must be administered every two to four weeks.

"Despite the benefits of treatment, staying on therapy can be a problem for some men," Dr. Rosen said. According to the survey, 64 percent of men had used two or more testosterone replacement medicines, and 28 percent of men reported that they had stopped taking their medication at some point.

New long-acting injections that only need to be administered five times in the first year following the initial injection and every 10 weeks thereafter are in development and may offer patients a convenient new option for treatment. A majority of men polled said five shots in a year would be an improvement over their current therapies.

Although testosterone levels decline with age, hypogonadism is not a natural consequence of the aging process. "Men with clinically diagnosed hypogonadism do not need to 'tolerate' the symptoms of low testosterone," Dr. Miner said. "There may be important physical benefits to treatment, such as increased muscle mass and a reduced risk for osteoporosis. We are only beginning to explore/appreciate the link between low testosterone and more serious medical conditions such as diabetes and cardiovascular disease."

The internet survey was conducted by Forrest W. Anderson during March and April and was sponsored by Endo Pharmaceuticals Inc., which is developing the first and only long-acting injectable testosterone replacement treatment in the U.S.

Testosterone undecanoate currently is pending U.S. Food and Drug Administration approval. Testosterone undecanoate was first approved in Europe in 2003 and is now marketed as Nebido in more than 80 countries by Bayer Schering Pharma AG.

ABOUT HYPOGONADISM

Hypogonadism, also known as low testosterone, is a common yet largely under-recognized and under-treated condition that affects an estimated 13.8 million men in the United States. Only 9 percent of American men with low testosterone are currently being treated with testosterone replacement therapy.

Low testosterone is associated with a broad range of physical, psychological and sexual symptoms including decreased energy and mood, fatigue, loss of muscle mass, decreased libido and erectile dysfunction. In addition, low testosterone is associated with other serious medical conditions including diabetes, cardiovascular disease and metabolic syndrome.

ABOUT ENDO

Endo Pharmaceuticals (Nasdaq: ENDP) is a specialty pharmaceutical company engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used to treat and manage pain, overactive bladder, prostate cancer and the early onset of puberty in children, or central precocious puberty (CPP). Its products include LIDODERM(R), a topical patch to relieve the pain of postherpetic neuralgia; Percocet(R) and Percodan(R) tablets for the relief of moderate-to-moderately severe pain; FROVA(R) tablets for the acute treatment of migraine attacks with or without aura in adults; OPANA(R) tablets for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate; OPANA(R) ER tablets for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time; and Voltaren(R) Gel, a nonsteroidal anti-inflammatory drug indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment such as those of the hands and the knees. Voltaren(R) Gel is owned and licensed by Novartis AG; SANCTURA(R) and its XR version for treatment of overactive bladder, VANTAS(R) for the palliative treatment of advanced prostate cancer, and SUPPRELIN(R) LA for the treatment of

early onset puberty in children. The company markets its branded pharmaceutical products to physicians in pain management, neurology, surgery, oncology, endocrinology and primary care. More information, including this and past press releases of Endo Pharmaceuticals, is available at www.endo.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the acquisition of Indevus, the company's financial position, results of operations, market position, product development and business strategy, as well as estimates of future net sales, future expenses, future net income and future earnings per share. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "intend," "guidance" or similar expressions are forward-looking statements. Because these statements reflect our current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this press release. These factors include, but are not limited to: the possibility that the transaction will not be completed, or if completed, not completed on a timely basis; the possibility that the acquisition of Indevus is not complementary to Endo; the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and pipeline products; competition in our industry, including for branded and generic products, and in connection with our acquisition of rights to assets, including intellectual property; government regulation of the pharmaceutical industry; our dependence on a small number of products and on outside manufacturers for the manufacture of our products; our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business; new regulatory action or lawsuits relating to our use of controlled substances in many of our core products; our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves; our ability to protect our proprietary technology; our ability to successfully implement our in-licensing and acquisition strategy; the availability of third-party reimbursement for our products; the outcome of any pending or future litigation or claims by the government; our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales; a determination by a regulatory agency that we are engaging in inappropriate sales or marketing activities, including promoting the "off-label" use of our products; the loss of branded product exclusivity periods and related intellectual property; and exposure to securities that are subject to market risk including auction-rate securities the market for which is currently illiquid; and

other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K, particularly the discussion under the caption "Item 1A, RISK FACTORS" in our annual report on Form 10-K for the year ended December 31, 2008, which was filed with the Securities and Exchange Commission on March 2, 2009. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

SOURCE Endo Pharmaceuticals

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http://www.redorbit.com/news/health/1703154/men_with_low_testosterone_see_multiple_doctors_before_being_diagnosed/