Henley's MicroLight 830 Laser Clinical Pre-Market Approval Study Nearing Completion At Baylor University's College of Medicine

Business Wire, Feb 19, 1999

SUGAR LAND, Texas--(BW HealthWire)--Feb. 19, 1999--Henley Healthcare Inc. (NASDAQ:HENL) Friday announced that its clinical investigational pre-market approval ("PMA") study utilizing the MicroLight 830(TM) Laser for the therapeutic treatment of Carpal Tunnel Syndrome ("CTS") is nearing completion.

The efficacy of the MicroLight 830 low level laser therapy ("LLLT") in the treatment of CTS is currently under evaluation in a multi-center randomized double-blind study at the Baylor College of Medicine's Hand Specialty Center, under the direction of Dr. David Lichtman, orthopedic surgeon and neurologist, and Dr. Stanton Moldovan, M.D., associate professor of Baylor College of Medicine.

CTS and repetitive stress injuries are the nation's most costly occupational health problems, costing in excess of $20 billion a year in workers' compensation. CTS is a common painful disorder of the wrist and hand, induced by compression on the median nerve between the inelastic carpal ligament and other structures within the carpal tunnel. According to the National Institute for Occupational Safety and Health, CTS affects seven percent of the U.S. population accounting for 14 percent of physician visits and 19 percent of hospital stays. The National Center for Health Statistics states that there are about 260,000 CTS operations performed each year and about 47 percent are work related.

Analysis of the patient results following the five-week laser treatment protocol and post-treatment follow-up data and clinical evaluations support the company's belief that LLLT is a viable non-surgical treatment modality for the many individuals suffering from CTS.

Dr. Moldovan, a neurologist who for the past 20 years has specialized in the treatment of patients with chronic pain said, "My participation in the MicroLight 830 Laser study is 80 percent completed. A certain number of patients have had a significant reduction in their pain symptoms. Other patients have been completely pain free. These patients are obviously very happy with their ability to function much better in everyday activities. However, as would be expected in a double-blind study, there are patients who have not shown such change in their pain symptoms or function."

"We are pleased to reach this turning point in what is often a lengthy clinical trial process in order to obtain FDA approval," said Michael Barbour, president and chief executive officer of Henley. "We are anxious to conclude these trials and report the findings to the FDA committee for their expedited review."

Henley Healthcare, a worldwide leader in the growing pain management industry, develops, manufactures and distributes products and related accessories used in the control of acute or chronic pain. Henley's diversified line of non-invasive physical medicine and rehabilitation products are used in the treatment of disabilities or injuries with therapeutic exercise and the application of various heat, fluidotherapy, traction, ultrasound or other modalities. The company is also awaiting FDA approval on its MicroLight 830(TM), a hand-held, low-energy (non-surgical) laser for the treatment of repetitive stress injuries such as carpal tunnel syndrome. For additional information on Henley Healthcare visit their Web site at www.henleyhealth.com.