



VERTOS MEDICAL'S PROSPECTIVE OUTCOMES STUDY DEMONSTRATES EFFICACY,  
VALIDATES SAFETY PROFILE OF *mild*<sup>®</sup>

ALISO VIEJO, Calif. – March 12, 2010 – Medical device company [Vertos Medical Inc.](#) has announced the release of positive results from its U.S. IRB I Patient Outcomes Trial, a prospective, investigational review board-approved, 75-patient study of *mild*<sup>\*</sup> for the treatment of lumbar spinal stenosis (LSS). Six-week clinical data have shown that patients treated with *mild* experience statistically and clinically significant improvement in both pain and functional ability. The data also confirmed *mild*'s safety, with no reports of patient complications related to the procedure or the devices.

The six-week follow-up data were unveiled at a continuing medical education (CME) meeting, chaired by Nagy Mekhail, M.D., Ph.D., at the 12<sup>th</sup> Annual Cleveland Clinic Pain Management Symposium in Coronado, Calif. on March 8.

As presented by study Co-Medical Monitor David Caraway, M.D., Ph.D. (St. Mary's Pain Relief Center, Huntington, W. Va.), key outcome measures at six weeks included changes in Visual Analog Score (VAS), which measures pain, and Oswestry Disability Index (ODI), which assesses functional ability. The study protocol defined success as a minimum two-point VAS improvement from baseline. The data showed that 67 percent of study participants met this success criterion, with an average improvement of 3.6 points from baseline across all patients. In addition, patients achieved an average ODI improvement from baseline of 17.9 points. The latter is noteworthy, said Caraway, as a U.S. Food and Drug Administration panel on orthopedic and rehabilitation devices has given guidance that a minimum 15-point change in ODI score from baseline is clinically significant.<sup>1</sup>

Dr. Caraway also noted that the data confirmed *mild*'s safety profile, with no dural tears, blood transfusions or other procedure or device-related complications having occurred. These findings are consistent with the results of a separate, recently published [acute safety study of \*mild\*](#), also presented as part of the CME meeting by Timothy Deer, M.D. (The Center for Pain Relief, Charleston, W. Va.)<sup>2</sup>

"*mild* provides a valuable therapeutic option for suffering patients, for whom we previously had only palliative treatments or open surgery," said Dr. Caraway.

The 75 study participants will continue to be followed over a period of two years.

**About *mild***

The first minimally invasive surgical treatment to provide immediate and lasting relief for patients by addressing a primary cause of lumbar spinal stenosis (LSS), *mild* was developed to provide a new option for patients who are no longer responding to pain medications and

epidural steroid injections (ESIs) but who are not candidates for more invasive surgery. Vertos estimates that, at any given point in time, this patient population numbers more than 650,000.<sup>3</sup> Treating LSS patients earlier and least invasively, which *mild* provides for, reduces overall health care costs.

**About Vertos Medical Inc.**

Vertos Medical was founded in 2005 to develop a minimally invasive method for lumbar spine decompression to treat patients with lumbar spinal stenosis (LSS), a degenerative, age-related narrowing of the lower spinal canal. Its first proprietary platform technology, called *mild*, is the least invasive surgical procedure for treating LSS, with no implants left behind. For more information, visit [www.vertosmed.com](http://www.vertosmed.com).

\* Vertos *mild* is FDA cleared for treating central canal stenosis of the lumbar spine.

<sup>1</sup> FDA, Center for Devices and Radiological Health, Orthopedic and Rehabilitation Devices Panel Meeting, Friday, September 9, 2005.

<sup>2</sup> Deer T, et al. New image-guided ultra-minimally invasive lumbar decompression method: the *mild* procedure. *Pain Physician* 2010; 13:35-41.

<sup>3</sup> Derived from the longitudinal CMS database.

###

**MEDIA CONTACT:**

Laura Nobles

310-795-0497

[laura@noblescommunications.com](mailto:laura@noblescommunications.com)