



LONG-TERM POST-STUDY FOLLOW-UP AND SINGLE-CENTER RANDOMIZED COMPARATIVE EFFICACY STUDY RESULTS DEMONSTRATE *mild*[®] SAFETY, EFFICACY

ALISO VIEJO, Calif. – March 7, 2011 – Medical device company [Vertos Medical Inc.](#) has announced the release of clinical study data demonstrating the long-term safety and efficacy of [mild](#) as well as its superior durability over epidural steroid injections (ESI) for treating lumbar spinal stenosis (LSS). The data, derived from two independent studies, was unveiled at a continuing medical education meeting chaired by Nagy Mekhail, M.D., Ph.D., at the 13th Annual Cleveland Clinic Pain Management Symposium in Sarasota, Fla. on March 6.

Year One Results: Post-Study Follow-up of the MiDAS I Clinical Trial

The long-term safety and efficacy of *mild* were validated by one-year post-study follow-up on patients from the MiDAS I ([mild](#)[®] **D**ecompression **A**lternative to Open **S**urgery) clinical trial. Presented by Timothy R. Deer, M.D. (The Center for Pain Relief, Charleston, W. Va.), the 12-month post-study follow-up data on 58 patients from 11 centers showed that *mild* patients continued to experience a statistically significant and clinically relevant reduction in pain and improvement in mobility as measured by the Visual Analog Score (VAS), Zurich Claudication Questionnaire (ZCQ) and SF-12v2[®] Quality of Life Survey. In addition, 74 percent of patients remained satisfied with the overall results of their *mild* treatment. No device or procedure-related serious adverse events were reported after 170 total procedures, which were primarily bilateral at one or two affected levels, in the 58 patients who were followed post-study through one year. These positive outcomes were consistent with the [six-month results](#) released in 2010 in the [final MiDAS I study report](#).

“The post-study follow-up data on *mild* present compelling evidence that the procedure offers a safe, effective and lasting treatment for lumbar spinal stenosis, as the significant response seen at three and six months was still present at one year across all four outcomes instruments,” said Dr. Deer. “This is very encouraging news for LSS patients who, before *mild*, have only had the palliative or open surgical treatment options for addressing their pain and immobility.”

mild Comparative Efficacy Study Results

Also unveiled at the continuing medical education meeting were the results of a randomized, controlled, double-blind comparison of *mild* versus epidural steroid injections, sponsored by Lora L. Brown, M.D. (Coastal Orthopedics, Bradenton, Fla.). The results of the single-center, 38-patient study further supported the excellent safety profile of *mild*, as well as ESI, while clearly demonstrating *mild*'s superior durability over ESI with respect to pain relief and patient satisfaction. Dr. Brown reported that there were no device or procedure-related serious adverse events between the two study groups and that both showed a significant week one

improvement in patient satisfaction and reduction in pain based on the VAS and ZCQ instruments. However, subsequent follow-up showed a marked difference between the groups. Following *mild* therapy, the positive patient satisfaction and pain relief results were durable through 12 weeks. With ESI, and in keeping with reports in current literature, a dramatic return of pain and associated patient dissatisfaction were observed after only week one with a return to baseline at 12 weeks.

“This study data shows that epidural steroid injections are safe and effective at treating LSS symptoms but only relieve those symptoms temporarily, and this is consistent with what we see in clinical practice,” said Dr. Brown. “In contrast, *mild* treats the source of the symptoms and in doing so has a more lasting effect. These findings represent a significant development in the treatment algorithm for LSS, as we may see *mild* effectively replacing ESI as an early treatment option for a potentially large population of patients.”

As presented by Dr. Mekhail, director of evidence-based pain management research and education at the Cleveland Clinic, *mild* is well positioned to fill the therapeutic gap in the care path of patients with lumbar spinal stenosis. He stated that *mild* should be considered after the failure of conservative treatment and before considering open surgical decompression or fusion in the treatment algorithm.

“We are very encouraged by the growing body of scientific data validating *mild*’s valuable and potentially paradigm-shifting role in the early treatment of LSS,” said James M. Corbett, president and chief executive officer of Vertos Medical. “By offering a safe, effective and lasting therapeutic option, we believe that *mild* has the potential to significantly improve the lives of LSS patients while also positively impacting the broader health-care system.”

About *mild*

mild is an image-guided percutaneous (through the skin) decompression laminotomy procedure used to treat patients with LSS, a condition diagnosed in 1.2 million patients annually in the United States.¹ A less invasive alternative to open or endoscopic surgery, *mild* safely and therapeutically reduces pain and increases mobility while maintaining structural stability.

About Vertos Medical Inc.

Vertos Medical was founded to advance the treatment of patients suffering with lumbar spinal stenosis (LSS), a degenerative, age-related narrowing of the lower spinal canal. Its proprietary platform technologies include *mild*, which offers a therapeutic intervention to treat LSS and achieve lumbar spine decompression utilizing 3-D imaging. For more information, visit www.vertosmed.com.

* Vertos *mild* is FDA cleared for treating lumbar spinal stenosis.

¹ Derived from the Longitudinal Medicare Database.

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