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Medovex Corporation's DenerveX System Demonstrates Clinical Benefits in Patients Suffering from Low Back Facet Joint Pain

Review of Real World Cases from Five Independent Sites Across Europe Demonstrated Reduction in Pain Scores and General Improvement of Health Metrics up to 6 Months Following Treatment as Evidenced by VAS_{BACK}, ODI and EQ-5D-5L.

ATLANTA, July 02, 2018 (GLOBE NEWSWIRE) -- Medovex Corp. (OTCQB:MDVX) ("Medovex" or the "Company"), the developer of the DenerveX® System, a new and novel device designed for enduring relief of Facet Joint Syndrome related to chronic back pain, a non-addictive, non-opioid drug alternative capable of restoring a patient to a more normal and active lifestyle, today announced the release of patient data that demonstrates clinical benefits of its DenerveX System in patients suffering from low back facet joint pain at 6 months post-treatment.

Facet Joint Syndrome (FJS) is among the leading causes of low back pain and affects millions globally. Typically manifesting from spinal osteoarthritis (OA), FJS is a painful, chronic condition whose treatment options, often temporary in nature, have remained unchanged in the past four decades.

Medovex's DenerveX is a novel, minimally invasive system developed to provide potential long-term relief via a combination of controlled thermal energy and rotational capsular tissue shaving of the bony structure to disrupt nociceptive signals and receptors. The Company hypothesized that use of this novel system would result in sustained pain relief and improved health metrics associated with mobility.

Methods

This prospective multicenter European cohort included patients with chronic intractable pain of the low back resulting from FJS who had failed conservative treatments for pain. Patients who were treated between July 2017 and February 2018 were evaluated for joint groupings treated, pain and quality of life as measured by the visual analog score (VAS), medication log, Oswestry Disability Index (ODI) and EQ-5D-5L. Follow-up was conducted at 1, 3, and 6 months post-treatment; data reported correspond to these time points.

Results

Results from 61 patients (60.7% females; average age 55.1±11.5 years) were evaluated. Prior to treatment, 47 patients regularly used one or more prescribed analgesics and had predominately undergone either physiotherapy (81.4%), spinal injections (86.4%), or both to help alleviate pain. A total of seven joint groupings were treated, with L3 – S1 (45.6%) and L4 – L5 (17.5%) being the most common. Baseline average VAS_{back} prior to treatment was 74.7±14.2mm, a 42.0±16.6 ODI score with a EQ-5D-5L score of 3 (out of 5). At 1, 3, and 6 months post-treatment, VAS_{back} decreased to 31.7±17.5mm (-57.5%), 25.5±22.9mm (-65.8%), and 17.7±18.3mm (-76.3%). Similarly, ODI 1, 3, and 6 months post-treatment decreased to 19.9±14.4 (-52.7%), 20.1±15.0 (-52.3%), and 14.1±9.9 (-66.4%). These decreases from baseline were consistently observed in more than half of the population. EQ-5D-5L scores post-treatment remained, on average 32% below baseline values.

Conclusions

Review of real world cases from five independent sites across Europe demonstrated reduction in pain scores and general improvement of health metrics up to 6 months following treatment as evidenced by VAS_{BACK}, ODI and EQ-5D-5L.

Jill Schweiger, Medovex Senior Vice President of Regulatory, Clinical and Quality stated, "We are pleased to present these initial results which affirm our belief that the DenerveX System provides significant quality of life improvement and relief from pain associated with facet joint syndrome. We look forward to releasing one-year data as soon as it is available."

The Company also plans in upcoming months to attend EuroSpine 2018 in Barcelona, Spain, NASS 2018 In Los Angeles, California and the annual DWG Meeting in Wiesbaden, Germany to support further sales and marketing activities. It also presented its DenerveX in Adelaide, Australia during the SSA (Spine Society of Australia) with sizeable audience interest, followed by ten successful first cases.

After successful INVIMA product approval in Colombia, first DenerveX cases are scheduled for July 14, 2018 in Medellin followed by additional cases in Bogota and other areas throughout Colombia.

In April, the Company was issued two US patents and a trademark covering the EU for “Rotacapsulation”.

- Patent No: US D810,290S Surgical Portal Driver
- Patent No: US 9,883,882 Minimally Invasive Methods for Spinal Facet Therapy to alleviate pain and associated surgical tools, kits and instructional media

About Medovex

Medovex was formed to acquire and develop a diversified portfolio of potentially ground breaking medical technology products. Criteria for selection include those products with potential for significant improvement in the quality of patient care combined with cost effectiveness. The Company's first pipeline product, the DenerveX System, is intended to provide long lasting relief from pain associated with facet joint syndrome. To learn more about Medovex Corp., visit **www.medovex.com**.

Safe Harbor Statement

Certain statements in this press release constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties, including without limitation those set forth in the Company's filings with the Securities and Exchange Commission (the "SEC"), not limited to Risk Factors relating to its business contained therein. Thus, actual results could be materially different. The Company expressly disclaims any obligation to update or alter statements whether as a result of new information, future events or otherwise, except as required by law.

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