FzioMed Receives Approval for Oxiplex® in Russia

The Associated Press

SAN LUIS OBISPO, Calif.--(BUSINESS WIRE)--Jan 22, 2013--FzioMed, a privately held medical device company based in San Luis Obispo, CA., is pleased to announce the approval of Oxiplex in Russia. Oxiplex is an absorbable, clear, viscoelastic gel that is applied during lumbar spine surgery immediately prior to wound closure.Based on four studies involving more than 500 patients, and nearly 10 years of commercial use benefitting more than 300,000 patients outside the U.S., Oxiplex has proven itself to be an effective surgical adjuvant that significantly reduces the effects of Failed Back Surgery Syndrome (FBSS) such as leg pain and neurological symptoms following surgery.Available in nearly 70 countries, including those in the European Union, Australia, Canada, Brazil, Mexico, South Korea and now Russia.

After a rigorous process in the largest country in the world, the Roszdravnadzor regulatory body has approved the sale of Oxiplex to physicians so that patients can experience the well-documented benefits of this adjunct to lumbar spine surgery.

“Russia presents a huge opportunity for FzioMed to expand the availability of Oxiplex to more than 140 million people, many of whom experience the same issues as we do with back and leg pain due to disc herniation,” said John Krelle, President and CEO of FzioMed.“Russian patients may now receive the added benefits of lower pain scores and reduced reoperation rates after lumbar surgery that peer reviewed published literature and more than 300,000 patients worldwide have demonstrated for more than a decade.” Oxiplex is not yet approved in the United States despite having demonstrated safety and effectiveness in clinical studies involving more than 500 patients.A Citizen Petition under 21 CFR 10.33 is still under review by FDA.

About FzioMed FzioMed is a privately held medical device company founded in 1996.The company develops, manufactures and commercializes absorbable surgical biomaterials based on its patented polymer science.FzioMed adhesion barriers are used in many surgical applications including spine, orthopedics, hand, tendon, peripheral nerve, gynecology and general surgery.Its spine gel is the #1 adhesion barrier gel for spine surgery worldwide and is distributed by Medtronic, DePuy and other independent distributors.For more information, please visitwww.fziomed.com.

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