



Javelin Pharmaceuticals Completes Open Label Safety Study of Dyloject(TM) -

Study Successfully Meets Objective -- Javelin on Track to File US New Drug Application in the fall of 2009

CAMBRIDGE, Mass., Jun 23, 2009 (BUSINESS WIRE) -- Javelin Pharmaceuticals, Inc. (NYSE Amex: JAV - News) today reported that it has completed its open-label multi-dose, multi-day, observational safety study of Dyloject in the United States and that the study successfully met its objective.

The objective of the study was to evaluate the safety of Dyloject following IV bolus administration of multiple doses over multiple days in patients aged 18 to 85 with acute post-operative pain. 856 patients successfully completed the study, receiving at least 8 doses of Dyloject over a 48 hour period. As with previous trials, Javelin plans to submit the results of this study for publication and presentation at an upcoming medical meeting.

The successful completion of this study satisfies the Company's goal of having well in excess of a 1000-patient safety data base for its Dyloject US NDA filing. The Company plans to file a New Drug application for Dyloject in the United States in the fall of 2009, at the same 37.5 mg dose used in the study.

"We were very pleased that the study met its objective and finished ahead of schedule." stated Eric Lang, M.D., Javelin's VP of Clinical Research. "856 patients successfully completed the study, receiving at least 8 doses of Dyloject. Javelin now has comprehensive safety data on greater than 1700 patients in our Integrated Summary of Safety for our NDA submission. We are on track to file a high quality NDA for Dyloject this fall. "

About The Study:

856 patients successfully completed the study, receiving at least 8 doses of Dyloject over two days of therapy. The study included 323 patients over 65 and 100 over age 75. Of note, over 400 patients completing the study received heparin, low weight molecular heparin or other anticoagulants concomitantly with the Dyloject therapy. In addition, two higher risk patient subgroups completed the study, approximately 40 patients with mild-to-moderate renal insufficiency and approximately 40 patients with mild hepatic insufficiency.

The study was designed as an open-label, multi-dose, multi-day, single-arm safety study of repeat-doses of Dyloject 37.5 or 50 mg (Intravenous Diclofenac Sodium) in male and female patients (18-85 years old). Enrolled patients presented with acute post-operative pain following abdominal (i.e., non-laparoscopic abdominal surgeries) or orthopedic (i.e., hip or knee joint replacement) surgery. These patients were expected to be eligible for multiple doses of a parenteral NSAID for multiple days in the acute, post-operative period to treat their pain and had no contraindication to receiving Dyloject. Patients received Dyloject 37.5 mg IV bolus every 6 hours (patients weighing \geq 95 kg received 50 mg IV bolus every 6 hours). Safety assessments were collected at baseline (immediately prior to starting Dyloject therapy) and at study discharge. Patient global assessments were obtained at study discharge or early termination.

Opioids or other standard postoperative analgesics, except NSAIDs, could be given as rescue medication. Patients received all other standard post-operative care as per the institution. Patients received Dyloject for a minimum of 48 hours or until they were transitioned to oral analgesics, discharged from the institution, or discontinued from the study, whichever came first.

Patients had follow-up visits at days 4-10 after their last dose of Dyloject and a safety follow-up telephone call 30-37 days post-last dose of Dyloject.

About Dyloject:

Dyloject is an injectable formulation of diclofenac in Phase 3 clinical development in the United States and marketed in the United Kingdom. Diclofenac is a prescription NSAID that is widely prescribed to treat postoperative pain. Dyloject has the potential to provide an attractive alternative to other NSAIDs for the treatment of post-operative pain, and to decrease the need for morphine or other opioids in this setting. There still exists an underserved medical need for safe and effective injectable NSAIDs in the hospital setting. NSAIDs are contraindicated in patients with advanced renal or hepatic disease and are used with caution in patients with mild to moderate renal and hepatic impairment, historically requiring reductions in dose.

NSAIDs are widely used postoperatively with opioids, e.g., morphine, to reduce opioid requirements by 30-60% and thereby decrease morphine-related side effects. Combining different types of pain medicines (called "multimodal analgesia") is the most

commonly advocated approach to acute postoperative pain management worldwide. Numerous studies of multimodal analgesia have shown that when patients are given an NSAID along with an opioid, dose requirements and adverse effects of the latter are reduced. Opioid side effects that are reduced by this dose-sparing approach include nausea, vomiting, and inadequate breathing.

About Javelin Pharmaceuticals, Inc.

With corporate headquarters in Cambridge, MA, Javelin applies innovative proprietary technologies to develop new drugs and improved formulations of existing drugs to target unmet and underserved medical needs in the acute pain management market. The Company has one marketed drug in the UK and three drug candidates in US Phase 3 clinical development. For additional information about Javelin, please visit the Company's website at <http://www.javelinpharmaceuticals.com>.

Forward Looking Statement

This news release contains forward-looking statements. Such statements are valid only as of today, and we disclaim any obligation to update this information. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other governmental regulation, our ability to obtain working capital, our ability to successfully develop and commercialize drug candidates, and competition from other pharmaceutical companies.

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