



Dyloject(TM) Significantly Reduces Moderate-to-Severe Pain in Pivotal Phase 3 Orthopedic Surgical Trial

Trial Successful, Javelin Pharmaceuticals on Track to Submit New Drug Application to US FDA in 2009

CAMBRIDGE, Mass., Dec 09, 2008 (BUSINESS WIRE) --

Javelin Pharmaceuticals (AMEX: JAV) announced today that its US product candidate Dyloject(TM) (diclofenac sodium for injection) met primary efficacy endpoints with robust statistical significance in the second of two large pivotal US Phase 3 efficacy studies in postsurgical patients with moderate-to-severe pain.

This successful Phase 3 pivotal trial in 277 orthopedic surgical patients randomized subjects to receive one of three treatments every 6 hours: Dyloject 37.5 mg, ketorolac 30 mg, or placebo. The primary efficacy measure was the area under the curve of pain intensity across time, plotted as the difference from pretreatment pain compared to placebo. This area was examined stepwise across intervals of 0-24, 0-48, 0-72, 0-96, and 0-120 hours. Dyloject 37.5 mg had statistically significant differences compared to placebo for its primary endpoint across all five time intervals ($P < 0.0001$ for each of the five intervals). Dyloject's efficacy was numerically although not statistically superior to ketorolac, which in turn was superior to placebo ($P < 0.0001$).

"I am very pleased by today's important data. We are well on track to submit a high quality New Drug Application for Dyloject to the US FDA in the second half of 2009. Our open label safety study of Dyloject is rapidly enrolling and will supplement the current US patient safety data base for the submission," stated Martin J. Driscoll, Javelin's CEO.

Javelin's Chief Medical Officer, Dr. Daniel Carr, stated, "It is gratifying to reconfirm Dyloject's robust effects in this trial in moderate-to-severe pain in postoperative orthopedic surgical patients, a substantial target population. The fact that doses of Dyloject lower than those previously felt necessary provided statistically significant pain relief in this trial is noteworthy. Further, Javelin has recently presented Phase 1 results demonstrating that Dyloject has minimal effects upon platelet function at the same dose tested in this study."

As in earlier trials, this latest Dyloject trial revealed no unexpected safety signals. Adverse events in the present study were similar for Dyloject and placebo. This finding is consistent with the absence to date of any untoward safety signal in the tens of thousands of patients who have received Dyloject in the UK since it was approved there a year ago. Complete analysis of data from this trial will be submitted for presentation at a medical meeting in 2009.

Javelin's first pivotal Phase 3 study of Dyloject evaluated patients with acute postoperative pain after abdominal or pelvic surgery, and successfully met its primary and secondary endpoints with statistical significance. Top-line results from that trial were reported in December 2007 and secondary data was presented in August 2008 at the World Congress of the International Association for the Study of Pain.

About Javelin's Pivotal Phase 3 Dyloject Study in Patients with Acute Postoperative Orthopedic Surgical Pain:

In this US multicenter, double-blind, placebo- and comparator-controlled study, postoperative orthopedic surgical patients (N=277) with moderate-to-severe pain received Dyloject, ketorolac, or placebo IV every 6 hours for up to 5 days. Supplemental analgesia with morphine was provided upon patients' request. Pain intensity was measured using a 0-100 mm Visual Analog Scale. The primary endpoint was the sum of pain intensity differences (SPID) versus pre-dosing pain, examined in a stepwise fashion over 0-24, 0-48, 0-72, 0-96, and 0-120 hours. The primary endpoints were highly statistically superior to placebo ($P < 0.0001$ for all time intervals tested). Default doses of Dyloject (37.5 mg) and ketorolac (30 mg) were adjusted for patients with low or high body weight, and mild renal or hepatic insufficiency.

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 nonsteroidal anti-inflammatory drug ("NSAID") that is widely prescribed to treat post-operative 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. In its pivotal UK registration trial, Dyloject's efficacy and safety were shown to be significantly superior to those of the IV formulation of diclofenac currently marketed in the UK. Each

dose of the competitive formulation requires buffering, dilution and slow infusion. Dyloject comes ready to use for immediate IV bolus administration, works faster, and according to a recent study, has the potential to save the UK NHS up to GBP 50 per postoperative patient. Dyloject is presently being marketed in the UK for the treatment of acute moderate-to-severe pain. Subsequent submissions and approvals in other European countries are anticipated through a regulatory strategy following the Mutual Recognition Process.

NSAIDs are widely used postoperatively with opioids, e.g., morphine, to reduce opioid doses by as much as thirty to fifty percent, 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. A number of 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 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 and their outcome, the FDA review process and other governmental regulation, our ability to obtain working capital, our ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies and other risks described in our annual and quarterly reports filed with the Securities and Exchange Commission.

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