



## **New Study Shows Javelin Pharmaceutical's Dyloject™ Well-Tolerated in High-Risk Patients with Impaired Renal and Hepatic Function**

CAMBRIDGE, Mass., Jun 15, 2009 (BUSINESS WIRE) -- Javelin Pharmaceuticals, Inc. (NYSE Amex: JAV - News) today reported encouraging findings from a new Phase I pharmacokinetic (PK) and safety study of Dyloject in patients with mild to moderate renal and mild hepatic impairment. Dyloject was well tolerated in these higher risk patient populations. The elimination rate of Dyloject's active ingredient diclofenac was statistically indistinguishable in all three patient groups compared with matched healthy controls. The Company plans to file a New Drug application for Dyloject in the United States during the fall of 2009, at the same dose used in these studies.

"Historically, IV nonsteroidal anti-inflammatory drugs (NSAIDs) such as ketorolac, the only IV NSAID approved in the US for moderate to severe pain, have been withheld from such patient populations or required major dose reductions because of concern for adverse effects" stated Daniel Carr, M.D., Javelin's President and Chief Medical Officer. "Dyloject's excellent tolerability in all study groups, and the insignificant changes in diclofenac distribution and clearance observed in patients with mild to moderate chronic renal insufficiency or mild hepatic impairment are most encouraging. These new PK and safety findings will be included in our NDA filing for Dyloject."

### **About The Study:**

This Phase I, open-label, single-dose study evaluated the safety and pharmacokinetics of Dyloject 37.5 mg given as an IV bolus over 15 seconds in subjects with mild or moderate chronic renal insufficiency and with mild chronic hepatic impairment compared to matched healthy adult volunteers. Additionally, healthy adult volunteers participated in a randomized, open-label, crossover study in which they received a single dose of Sporanox<sup>(R)</sup> (itraconazole 200 mg with 8 gm of the solubilizing agent HPBCD) given as an IV infusion over 60 minutes to compare the PK and safety of HPBCD in the two medications. The 37.5 mg dose of Dyloject is formulated with 0.3 gm of HPBCD. A total of 40 subjects were treated in this study including 13 patients with mild to moderate renal insufficiency (creatinine clearance 30-80 ml/min), 8 patients with mild hepatic impairment and 19 healthy adult volunteers. Patients continued to take their prescribed medications to treat hypertension, diabetes and high cholesterol.

### **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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