



## **Javelin Pharmaceuticals Submits Dyloject(TM) New Drug Application to FDA for Management of Acute Moderate-to-Severe Pain in Adults**

### **Comprehensive Submission Includes Data from 16 Clinical Studies**

CAMBRIDGE, Mass., Dec 02, 2009 (BUSINESS WIRE) -- Javelin Pharmaceuticals, Inc. (NYSE Amex: JAV), a leading developer and marketer of specialty pharmaceutical products for pain management, today announced that it has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for its investigational product candidate, Dyloject(TM) (diclofenac sodium) Injection, for the management of acute moderate-to-severe pain in adults. If approved, Dyloject will be the first IV non-steroidal anti-inflammatory drug (NSAID) marketed in the United States as a single agent for the management of acute moderate-to-severe pain in adults since ketorolac in 1990.

"Our NDA submission for Dyloject is a significant milestone for Javelin. It reflects our commitment to patients suffering from acute moderate-to-severe pain, whose need for effective and safe analgesia in both the inpatient and day surgery settings is currently underserved," stated Martin J. Driscoll, CEO of Javelin Pharmaceuticals, Inc. "I am proud of my fellow colleagues who worked diligently to complete today's NDA submission and the many investigators who participated in our Dyloject clinical development program."

Javelin's comprehensive submission includes 16 clinical studies evaluating over 2000 subjects dosed with Dyloject. It includes over 1300 US patients in two multi-dose, multiple-day placebo-controlled Phase 3 pivotal efficacy studies and one multi-dose, multiple-day open label safety study. As previously reported, patient populations included the elderly (65 years of age and older) and patients with mild-to-moderate renal or mild hepatic insufficiency. In addition, over 400 Dyloject-treated patients received blood thinning agents during routine post-operative care. The two major efficacy trials for Dyloject achieved their primary endpoints (summary of pain intensity differences over the duration of the trial) and also showed reductions in postoperative opioid consumption of 43.5% and 61.5% compared to placebo. Moreover, the NDA submission includes pharmacovigilance data on Dyloject(R) from the UK, where it has been marketed following its approval in the fourth quarter of 2007.

Diclofenac sodium, the active pharmaceutical ingredient in Dyloject is one of the most widely prescribed NSAIDs. Since its initial approval in the 1980s approximately 1 billion patient days of treatment with diclofenac are estimated worldwide. It is approved and marketed in a variety of forms in the US including several oral formulations, a topical gel, patch and ophthalmic drops. However, an injectable formulation is not yet available in the United States.

The Company believes there is a significant unmet medical need for non-opioid agents for the management of pain in patients with acute moderate-to-severe pain. Opioids such as morphine may cause undesirable side effects including nausea, vomiting, constipation, sedation, cognitive impairment and respiratory depression. Decreasing or eliminating the need for opioid medication can reduce many of these side effects.

#### About Dyloject:

Dyloject has the potential to provide a novel alternative for the management of acute moderate-to-severe pain as a single agent. In clinical studies it reduced the need for morphine or other opioids. It is well established that a reduction in opioid requirements by at least 30% is necessary to effect a decrease in opioid-related side effects. Combining different types of pain medicines ("multimodal analgesia") is the most commonly advocated approach to postoperative pain management. Numerous studies of multimodal analgesia have shown that this strategy for maintaining effective pain relief while reducing opioid dose requirements often decreases the incidence of opioid related adverse events.

#### About Javelin

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 approved drug in the UK, a submitted NDA for Dyloject and two drug candidates in US Phase III 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 future outcomes. Forward-looking statements include statements regarding the potential for FDA to accept our filing and approve our NDA for Dyloject, our belief in the strength of the data supporting the NDA for Dyloject, and statements regarding unmet medical needs and Dyloject's commercial and therapeutic potential. The inclusion of forward-looking statements should not be regarded as a representation by Javelin that its past and future plans will be achieved. Actual results may be materially different from those included in this press release, past press releases and other public filings due to the high degree and inherent risks involved in drug discovery, development and commercialization.

Drug discovery, development and commercialization involve a high degree of risks and uncertainties, including: The materiality of Dyloject's success to Javelin, and uncertainty as to whether Dyloject and/or our other drug candidates Rylomine and Ereska, will receive regulatory approvals or be successfully commercialized; the potential that the FDA may not accept Dyloject's NDA for review in a timely fashion, or that the clinical data and other submission materials included in the Company's NDA for Dyloject may not support our product candidate's safety and efficacy; that the incidence, frequency and severity of adverse side effects associated with this product candidate may be greater than anticipated, which could significantly delay or prevent its US regulatory approval; that the FDA may require the Company to perform additional non-clinical or clinical studies; the potential that the FDA may introduce additional requirements that need to be completed before or after regulatory approval; that the Companies manufacturing process for Dyloject does not meet all regulatory requirements; that our reliance on third parties to conduct clinical trials, regulatory submissions, manufacturing, and other vital elements of Dyloject's and our other product candidates development programs and the risk that third party performance, if found to be substandard, could delay or prevent the approval of Dyloject or our other product candidates.

In addition, other factors that might cause additional material differences to our business include, among others; uncertainties related to the ability to attract and retain development and commercialization 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 inherent competition from other pharmaceutical companies.

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