



FDA Accepts Javelin Pharmaceuticals' Dyloject(TM) New Drug Application for Formal Review

NDA for Management of Acute Moderate-to-Severe Pain Includes Data from 16 Clinical Studies

CAMBRIDGE, Mass., Feb 02, 2010 (BUSINESS WIRE) -- Javelin Pharmaceuticals, Inc. (NYSE Amex: JAV), a leading developer and marketer of specialty pharmaceutical products for pain management, today announced that its New Drug Application (NDA) submitted on December 2, 2009 to the US Food and Drug Administration (FDA) for its investigational product candidate, Dyloject(TM) (diclofenac sodium) Injection, has been accepted for formal review. The Company expects to learn the Dyloject NDA's PDUFA date from the FDA in the next few weeks. The NDA is in support of US marketing approval and registration of Dyloject 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.

"Acceptance by the FDA of Javelin's comprehensive NDA submission for Dyloject marks a significant regulatory milestone towards our goal of commercialization of Dyloject in the U.S. My colleagues and I are proud of this major achievement and are committed with Javelin's merger partner, Myriad Pharmaceuticals, Inc. to developing and commercializing new alternatives for patients suffering from acute moderate-to-severe pain. We look forward to working with the FDA to facilitate the review of the Dyloject NDA," stated Eric Lang, MD, VP Clinical Research of Javelin Pharmaceuticals, Inc.

Javelin's NDA 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 postoperative care. The two major efficacy trials for Dyloject achieved their primary endpoints (summary of pain intensity differences over the duration of the trial). 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 nonopioid agents for the management of pain in patients with acute moderate-to-severe pain. Opioids such as morphine can cause undesirable side effects including nausea, vomiting, constipation, sedation, cognitive impairment and respiratory depression. Decreasing or eliminating the need for opioid medication may 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 by approximately 50%. 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>.

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 review 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 review Dyloject's NDA 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.

Forward Looking Statement Regarding the Merger between Javelin Pharmaceuticals, Inc. and Myriad Pharmaceuticals, Inc.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements relating to: the timing and expected benefits of the proposed merger; Javelin's product candidate Dyloject, and its potential for FDA approval and the ability to generate future revenues for the combined company; the expected number of shares of Myriad Pharmaceuticals common stock to be issued in the merger, which could increase based on a number of factors, including the timing of FDA approval of Dyloject, if at all, and the exercise of options to purchase Javelin common stock prior to the consummation of the merger; and information related to Myriad Pharmaceuticals' product candidates. These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by forward-looking statements.

These risks and uncertainties include, but are not limited to: general business and economic conditions; the failure of the Myriad Pharmaceuticals or Javelin stockholders to approve the merger or the failure of either party to meet any of the other conditions to the closing of the merger; the failure to realize the anticipated benefits from the merger or delay in realization thereof; the difficulty of developing pharmaceutical products, and obtaining regulatory and other approvals; and the uncertainty regarding achieving market acceptance of any products for which regulatory approval is obtained; and other factors discussed under the heading "Risk Factors" in Myriad Pharmaceuticals' Annual Report on Form 10-K for the year ended June 30, 2009, which has been filed with the SEC, as well as any updates to those risk factors filed from time to time in Myriad Pharmaceuticals' Quarterly Reports on Form 10-Q or Current Reports on Form 8-K. All information in this press release is as of the date of the release, and Myriad Pharmaceuticals undertakes no duty to update this information unless required by law.

Important Additional Information Will be Filed With the SEC

This press release may be deemed to be solicitation material regarding the proposed merger of Myriad Pharmaceuticals and Javelin. In connection with the proposed merger, Myriad Pharmaceuticals intends to file with the SEC a registration statement on Form S-4, which will include a joint proxy statement/prospectus of Myriad Pharmaceuticals and Javelin and other relevant materials in connection with the proposed merger, and each of Myriad Pharmaceuticals and Javelin intend to file with the SEC other documents regarding the proposed merger. The final joint proxy statement/prospectus will be mailed to the stockholders of Myriad Pharmaceuticals and Javelin. **INVESTORS AND SECURITY HOLDERS OF MYRIAD PHARMACEUTICALS AND JAVELIN ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND THE OTHER RELEVANT MATERIAL CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MYRIAD PHARMACEUTICALS, JAVELIN AND THE PROPOSED MERGER.**

The joint proxy statement/prospectus and other relevant materials (when they become available), and any and all documents filed with the SEC, may be obtained free of charge at the SEC's web site at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Myriad Pharmaceuticals by directing a written request to Myriad Pharmaceuticals, Inc., 320 Wakara Way, Salt Lake City, Utah 84108, Attention: Investor Relations, and by Javelin by directing a written request to Javelin Pharmaceuticals, Inc., 125 Cambridge Park Drive, Cambridge, MA 02140, Attention: Investor Relations.

Myriad Pharmaceuticals, Javelin and their respective executive officers and directors and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Myriad Pharmaceuticals and Javelin in connection with the proposed merger. Information about the executive officers and directors of Myriad Pharmaceuticals and their ownership of Myriad Pharmaceuticals common stock is set forth in Myriad Pharmaceuticals' annual report on Form 10-K for the year ended June 30, 2009, filed with the SEC on September 28, 2009. Information regarding Javelin's directors and executive officers is available in its annual report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 12, 2009, and the proxy statement for Javelin's 2009 annual meeting of stockholders, filed with the SEC on April 30, 2009.

Certain directors and executive officers of Javelin may have direct or indirect interests in the merger due to securities holdings, pre-existing or future indemnification arrangements and rights to severance payments if their employment is terminated prior to or following the merger. If and to the extent that any of the Myriad Pharmaceuticals or Javelin participants will receive any additional benefits in connection with the merger, the details of those benefits will be described in the joint proxy statement/prospectus relating to the merger. Investors and security holders may obtain additional information regarding the direct and indirect interests of Myriad Pharmaceuticals, Javelin and their respective executive officers and directors in the merger by reading the joint proxy statement/prospectus regarding the merger when it becomes available.

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