



## **Javelin Presents PMI-150 (Intranasal Ketamine) Data at Premier Department of Defense Scientific Meeting**

### **Analgesic blood levels rapidly achieved, reliably sustained during repeat dosing**

CAMBRIDGE, Mass., Aug 12, 2008 (BUSINESS WIRE) -- Javelin Pharmaceuticals, Inc. (AMEX:JAV), a leading developer of novel products for pain management, is presenting data today on its PMI-150 drug candidate (intranasal ketamine for acute pain) at the Department of Defense's (DoD) 2008 Advanced Technology Applications for Combat Casualty Care (ATACCC) Conference.

Javelin will present two posters, the first, "The Pharmacokinetics, Safety, and Tolerability of Repeat Doses of Intranasal Ketamine in Healthy Volunteers," presents the pharmacokinetic results following repeated intranasal administration of PMI-150 according to a set dosing schedule. According to peer-reviewed literature, plasma ketamine concentrations in the range of 50 - 150 ng/ml produce analgesia. Analysis of the pharmacokinetic data showed that the dosing schedule followed by the study resulted in mean plasma ketamine concentrations within the target analgesic range. In addition, intranasal ketamine was shown to be well tolerated.

The second poster, "Relative Analgesic Potencies of Intranasal Ketamine and Intranasal Morphine Compared to Intravenous Morphine," presents a meta-analysis of the efficacy results from a PMI-150 (1) and a Rylomine (2) post-operative dental study to calculate the analgesic potency equivalence of PMI-150 and Rylomine to intravenous (IV) morphine. The analysis from these 2 studies demonstrated that a single PMI-150 device (delivering 30mg ketamine hydrochloride) and a single Rylomine device (delivering 7.5mg morphine base) provide the equivalent analgesia as a 5mg dose of IV morphine.

"These results provide further support for the potential of PMI-150 as a viable alternative to injected morphine for pain control in the modern battlefield," said Dr. Daniel Carr, Javelin's Chief Medical Officer and President. "Blood levels of ketamine are promptly reached and reliably sustained during continued dosing."

#### About ATACCC

ATACCC is the DoD's premier scientific meeting that addresses critical advances in trauma medicine and the unique medical needs of the war fighter. The conference will focus on the growing and changing operational issues and identifies current and future technologies that can be used to meet these increasingly complex goals. For more information on ATACCC visit: <https://www.usacc.org/ATACCC/index.htm>.

#### About PMI-150

The Company is developing PMI-150, a proprietary nasal formulation of ketamine, for several intended indications, such as an analgesic for acute pain. Javelin believes that PMI-150 is optimized for use as a pain medication and may offer a safe, non-opioid alternative for the treatment of moderate-to-severe pain.

Prior randomized, double-blind, placebo-controlled, phase II clinical studies of PMI-150 have demonstrated rapid, statistically significant relief of moderate-to-severe postoperative and breakthrough pain. These study results have been published in peer-reviewed journals (Carr et al, Pain 2004; 108: 17-27; and Christensen et al, Acute Pain 2007; 9: 183-192), and presented at meetings of the American Society for Clinical Pharmacology and Therapeutics, the American Society of Clinical Oncology, and in a plenary session of the Advanced Technology Application for Combat Casualty Care. Following this last presentation, the U.S. Department of Defense awarded the Company approximately \$4.3 million in funding extensions to develop PMI-150. This award reflected the need for a fast-acting, noninvasive, and non-sedating alternative to the intravenous and oral medications commonly used for treatment of combat-related injuries.

On June 4, 2008, Javelin was awarded a patent in the European Union that extends patent protection for PMI-150 into 2023. European Patent No. 1 562 566 B1, entitled: "Analgesic Compositions Comprising NMDA Receptor Antagonists and Benzalkonium Chloride," is a commercially important patent that offers broad protection in the major EU market countries (G5) as well as in over twenty additional Member States of the European Patent Convention. This new patent is the European counterpart to Javelin's U.S. Patent No. 7,273,889 that issued in September, 2007.

At the 24th Annual Meeting of the American Academy of Pain Medicine in February 2008, Javelin presented a poster entitled,

"Relative Analgesic Potencies of Intranasal Ketamine and Intranasal Morphine Compared to Intravenous Morphine." The poster presented a meta-analysis of the efficacy results from 2 post-operative dental studies, one study with PMI-150 and one study with Rylomine (intranasal morphine), to calculate the analgesic potency equivalence of PMI-150 and intravenous (IV) morphine. The analysis from these 2 studies demonstrated that a single PMI-150 device (delivering 30mg ketamine hydrochloride) and a single Rylomine device (delivering 7.5mg morphine) provide the equivalent analgesia as a 5mg dose of IV morphine.

#### About Rylomine(TM)

Rylomine (intranasal morphine) is currently in Phase 3 development in the United States, for moderate-to-severe pain in supervised healthcare settings. It employs the patented and proprietary, Chysis(R) drug-delivery platform to adhere and regularize the kinetics of morphine to and across the nasal mucosa. After use, a negligible amount of morphine remains in the dispenser, avoiding the risk of scavenging and abuse of discarded devices. Data from clinical studies have demonstrated that Rylomine has similar efficacy to intravenous morphine.

#### 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 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.

#### JAV-G

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