February 22, 2008

Hisamitsu Pharmaceutical Co., Inc.

Press Release relating to FDA Approval for SALONPAS® PAIN RELEAF PATCH (code: FS-67, topical analgesic product) under NDA

Hisamitsu Pharmaceutical Co., Inc. (Representative Director, President and CEO: Hirotaka Nakatomi, "Hisamitsu") announced today that the company has obtained the U.S. FDA approval for its newly developed topical analgesic product, SALONPAS® PAIN RELIEF PATCH code-named FS-67, the new drug application (NDA) of which was filed earlier. The product contains methyl salicylate and l-menthol as active ingredients and will be manufactured at Hisamitsu's Tosu Plant and is planned to be marketed as an over-the counter (OTC) topical pain-reliever under the names of SALONPAS® PAIN RELIEF PATCH and SALONPAS® ARTHRITIS PAIN by Hisamitsu America Inc. (Headquarters: Torrance CA, President: Kosuke Sugiyama).

The product is the first FDA-approved OTC topical analgesic patch with great elasticity and snugness (7cm x 10cm) and it has proved to be significantly more effective than placebo patches in a series of well-controlled, double-blind clinical trials on patients having mild to moderate muscle pains, the fact of which endorses the approved indication for "Temporary relief of mild to moderate aches and pains of muscles and joints associated with arthritis, sprains, bruises and simple backache."

The directions of use: Apply one patch and keep it on for 8 to 12 hours. If pain lasts after using the first patch, apply a second patch and keep it on for 8 to 12 hours.

Hisamitsu is now getting ready for multiple pediatric clinical trials to assess the safety and effectiveness of the product used for children under 18 years of age.

Hisamitsu will further strive to promote its corporate philosophy "Patch and Care of People around the World" by launching this new patch product in the U.S.OTC market of pain relievers such as oral drugs, other patches, lotions, gels, and ointments.

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