New Drug Application Submitted to FDA for Investigational Analgesic Tapentadol Immediate Release Tablets

RARITAN, N.J., Jan 23, 2008 /PRNewswire-USNewswire via COMTEX News Network/ -- Johnson & Johnson Pharmaceutical Research & Development, L.L.C. announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tapentadol hydrochloride immediate release (IR) tablets, an investigational oral analgesic for the relief of moderate to severe acute pain.

According to the American Pain Foundation, more than 25 million Americans experience acute pain each year as a result of injuries or surgeries, and a recent study estimated that 42 percent of U.S. hospital emergency department visits were due to pain-related problems.

Tapentadol is a novel investigational, centrally acting oral analgesic. It has a unique profile with two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition in a single molecule. It is being developed in immediate-release and extended-release formulations.

Mu-opioid agonists are drugs that bind to mu-opioid receptors in the central nervous system. These drugs modify sensory and affective (mood) aspects of pain, inhibit the transmission of pain at the spinal cord and affect activity at parts of the brain that control how pain is perceived. Norepinephrine reuptake inhibitors are a type of central nervous system medication that increase the level of norepinephrine in the brain by inhibiting its re-absorption into nerve cells; these compounds have analgesic properties.

The submission is based on a full clinical development program for tapentadol. The program includes two Phase 3 multi-center studies that explored the efficacy and safety of multiple doses of the tapentadol IR formulation either for the treatment of acute pain in patients undergoing bunionectomy surgery or for patients with degenerative, end-stage joint disease of the hip or knee. The data from these clinical trials suggest that tapentadol has efficacy comparable to strong opioids.

Bunionectomy is a standard foot surgery. The predictable level of moderate to severe pain for several days following this surgery makes bunionectomy an appropriate model for assessing the efficacy of potent analgesics.

Data also were submitted to the FDA from an additional Phase 3 study that supported the safety profile of multiple doses of tapentadol IR in the treatment of outpatients with low back pain or pain from osteoarthritis of the hip or knee.

More than 1,800 patients have been treated with tapentadol IR tablets in clinical trials to date.

The most common adverse reactions in tapentadol Phase 2/3 multiple dose, placebo- and active-controlled efficacy and safety studies (10%) were nausea, dizziness, vomiting, somnolence (sleepiness) and headache.

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) is conducting the clinical program for tapentadol in the United States. J&JPRD submitted the new drug application (NDA) for tapentadol on behalf of Ortho-McNeil-Janssen Pharmaceuticals, Inc., an affiliated company that will hold the NDA for tapentadol. Upon FDA approval, PriCara(TM), Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., will market tapentadol in the United States.

This filing represents the ongoing commitment of J&JPRD and PriCara(TM) to bring new and innovative products to patients and physicians for the treatment and management of pain.

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Ortho-McNeil-Janssen Pharmaceuticals, Inc. are wholly owned subsidiaries of

Johnson & Johnson.

Grunenthal, a privately owned pharmaceutical company based in Aachen, Germany, discovered and started development of tapentadol. Grunenthal and J&JPRD have shared development responsibilities for tapentadol for acute and chronic pain conditions since the companies signed a licensing agreement for tapentadol in 2003.

Grunenthal licensed marketing rights to tapentadol to Ortho-McNeil-Janssen Pharmaceutical, Inc. for the United States, Canada and Japan. Grunenthal maintains marketing rights in Europe and other parts of the world. A trade name for the product has not

yet been determined.

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) is headquartered in Raritan, New Jersey (USA), and has nine sites throughout Europe and the United States. J&JPRD employs approximately 3,500 people and is leveraging drug discovery, drug evaluation, and drug development in a variety of therapeutic areas to address unmet medical needs worldwide. The company's major therapeutic areas of focus include hematology, oncology, infectious disease, obesity and metabolic disorders, neurology and psychiatry, pain and women's health.

PriCara(TM), Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

PriCara(TM), a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., is a major health care company in the United States dedicated to the needs of primary care providers who serve a vital role on the frontline of medicine. For more information about the company, please visit http://www.PriCara.com.

[This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from expectations and projections of J&JPRD. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of the Johnson & Johnson Annual Report on Form 10-K for the fiscal year ended December 31, 2006. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov or on request from J&JPRD or Johnson & Johnson. J&JPRD does not undertake to update any forward-looking statements as a result of new information or future events or developments.]

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