



## **FDA APPROVES TAPENTADOL IMMEDIATE-RELEASE TABLETS FOR RELIEF OF MODERATE TO SEVERE ACUTE PAIN**

Raritan, NJ – November 21, 2008 – Millions of Americans with moderate to severe acute pain and their health-care providers will soon have a new treatment option. Today, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., (J&JPRD), announced that the U.S. Food and Drug Administration (FDA) approved tapentadol immediate-release tablets for the relief of moderate to severe acute pain in adults 18 years of age or older.

Tapentadol is a new centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition.

Tapentadol tablets have been approved in 50 mg, 75 mg and 100 mg doses.

The approval was based on data from clinical studies involving more than 2,100 patients. The studies, which were presented at the 27th Annual Scientific Meeting of the American Pain Society earlier this year, showed that tapentadol provided significant relief of moderate to severe acute pain compared to placebo.

Following today's FDA approval, and as per Federal regulation for all controlled substances, tapentadol will be reviewed by the U.S. Drug Enforcement Agency for scheduling, and it cannot be sold until it receives a scheduling classification.

A trade name for tapentadol has not yet been determined.

“We are pleased with the FDA's approval today. Tapentadol represents a new treatment option in pain management, and I am excited that we are able to bring this new choice to patients who are suffering from pain,” said Joanne Waldstreicher, M.D., Global Head, Research and Development for CNS/Internal Medicine, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

More than 25 million Americans experience acute pain each year as a result of injuries or surgery, and it is the most common reason people seek medical attention.

“We welcome new proven treatment options that can help people with pain,” said Mark Rasmussen, President/CEO, The National Pain Foundation, Denver, CO.

PriCara<sup>®</sup>, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., will market tapentadol in the United States. J&JPRD and Ortho-McNeil-Janssen Pharmaceuticals, Inc. are wholly owned subsidiaries of Johnson & Johnson.



### **Approval Based on Results of Phase 3 Studies**

Multiple Phase 3 studies presented at the 27<sup>th</sup> Annual Scientific Meeting of the American Pain Society in May showed tapentadol offers patients significant relief of their pain when compared to placebo, and that the medicine was generally well tolerated in these studies.

The studies were conducted in different patient groups, including those who had a bunionectomy, a standard foot surgery associated with predictable levels of moderate to severe pain, and in those with pain from end-stage joint disease. ([http://www.jnj.com/connect/news/all/20080509\\_160002](http://www.jnj.com/connect/news/all/20080509_160002); [http://www.jnj.com/connect/news/all/20080509\\_160000](http://www.jnj.com/connect/news/all/20080509_160000))

At the same meeting, a Phase 3 safety study of tapentadol immediate-release tablets was presented. This study evaluated tapentadol in patients with low back pain or pain from osteoarthritis of the hip or knee. It demonstrated that tapentadol offers pain relief and is generally well tolerated. ([http://www.jnj.com/connect/news/all/20080509\\_160001](http://www.jnj.com/connect/news/all/20080509_160001))

### **Two Mechanisms of Action**

Mu-opioid agonists are drugs that bind to and activate mu-opioid receptors in the central nervous system. These drugs modify sensory and affective 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 increases the level of norepinephrine in the brain by inhibiting its re-absorption into nerve cells; these compounds have analgesic properties.

### **IMPORTANT SAFETY INFORMATION**

Tapentadol is contraindicated in any situation where mu-opioid agonists are contraindicated (i.e., significant respiratory depression, acute or severe bronchial asthma or hypercapnia); in patients with paralytic ileus; or in patients currently using or within 14 days of using monoamine oxidase inhibitors (MAOI).

Due to its mu-opioid receptor agonism, respiratory depression is a possible adverse event of tapentadol. Tapentadol should be administered with caution to the elderly, debilitated patients, and patients with conditions accompanied by hypoxia, hypercapnia or decreased respiratory reserve such as: asthma, chronic obstructive pulmonary disease or cor pulmonale, severe obesity, sleep apnea syndrome, myxedema, kyphoscoliosis, CNS depression, or coma. Patients receiving other  $\mu$ -opioid agonist analgesics, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol, opioids or illicit drugs) concomitantly with tapentadol may exhibit an additive CNS depression. Interactive effects resulting in respiratory depression, hypotension, profound sedation, or coma may result if these drugs are taken in combination with tapentadol. When such combined therapy is contemplated, a dose reduction of one or both agents should be considered.



Like other drugs with mu-opioid agonist activity, tapentadol should not be used in patients susceptible to increased intracranial pressure, impaired consciousness, or coma. It should be used with caution in patients with head injury, intracranial lesions, or other sources of preexisting increased intracranial pressure.

Tapentadol should be used with caution in patients with pancreatic or biliary tract disease, and moderate hepatic impairment. Because elderly patients are more likely to have decreased renal and hepatic function, consideration should be given to starting elderly patients with the lower range of recommended doses.

Tapentadol can be abused in a manner similar to other mu-opioid agonists, legal or illicit. This should be considered when prescribing or dispensing tapentadol in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. Abuse of tapentadol poses a risk of overdose and death. This risk is increased with concurrent abuse of tapentadol with alcohol and other substances. Monitor patients closely for signs of abuse and addiction.

Tapentadol may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. Tapentadol should be prescribed with care in patients with a history of a seizure disorder or any condition that would put the patient at risk of seizures.

The development of a potentially life-threatening serotonin syndrome may occur with use of SNRI products, including tapentadol, particularly with concomitant use of serotonergic drugs such as SSRIs, SNRIs, TCAs, MAOIs and triptans, and with drugs which impair metabolism of serotonin (including MAOIs).

The most common adverse events ( $\geq 10\%$  in any tapentadol dose group) in clinical trials were nausea, dizziness, vomiting, somnolence and headache.

For information about the package insert for tapentadol, consult the FDA Web site.

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

Johnson & Johnson Pharmaceutical Research & Development, L.L.C., (J&JPRD) is a wholly owned subsidiary of Johnson & Johnson, the world's most broadly based producer of health care products. J&JPRD is headquartered in Raritan, N.J., and has facilities throughout Europe, the United States and Asia. J&JPRD is leveraging drug discovery and drug development in a variety of therapeutic areas, including CNS, Internal Medicine and Oncology, to address unmet medical needs worldwide. More information can be found at <http://www.jnjpharmarnd.com/>.

**PriCara<sup>®</sup>, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.**

PriCara<sup>®</sup>, 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 [www.PriCara.com](http://www.PriCara.com).

### **Grünenthal**

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

Grünenthal licensed marketing rights to tapentadol to Ortho-McNeil-Janssen Pharmaceutical, Inc. for the United States, Canada and Japan. Grünenthal maintains marketing rights in Europe and other parts of the world.

[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 the Company's expectations and projections. 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 30, 2007. Copies of this Form 10-K, as well as subsequent filings, are available online at [www.sec.gov](http://www.sec.gov) <<http://www.sec.gov>>, [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.]

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