



NUCYNTA™ (tapentadol) CII Immediate Release Tablets Now Available for Relief of Moderate to Severe Acute Pain

New Centrally Acting Prescription Medicine Treats Pain in Two Ways

Raritan, NJ - June 23, 2009 - Patients suffering from acute pain and healthcare professionals who treat pain have a new treatment option: NUCYNTA™ (tapentadol) CII immediate release tablets. This new medication for the relief of moderate to severe acute pain in patients 18 years of age or older is now available by prescription only in 50-mg, 75-mg and 100-mg tablets, announced PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

NUCYNTA™ binds to mu-opioid receptors and inhibits norepinephrine re-uptake. Although the exact mechanism of action is not known, these two mechanisms, which affect established pain pathways, are thought to be responsible for pain relief with NUCYNTA™.

More than 25 million Americans experience acute pain each year as a result of injuries or surgery, and acute pain is the most common reason people seek medical attention. Pain is often undertreated, and acute pain in particular may cause serious medical complications, impair recovery from injury or procedures, and may progress to chronic pain if not properly managed.

"In clinical trials, NUCYNTA™ provided patients with effective pain relief and was shown to have fewer of the gastrointestinal side effects often reported with prescription pain medications that act on mu-opioid receptors," said Perry Fine, M.D., Professor of Anesthesiology, University of Utah, Salt Lake City, and consultant to PriCara®.

"This new treatment option offers the potential to improve treatment outcomes for acute pain patients."

On November 20, 2008, the U.S. Food and Drug Administration (FDA) approved NUCYNTA™ for the relief of moderate to severe acute pain in patients 18 years of age or older. The U.S. Drug Enforcement Agency has placed NUCYNTA™ into Schedule II of the Controlled Substances Act.

The FDA approval of NUCYNTA™ was based on data from clinical studies involving more than 2,100 patients with acute pain. The studies found that NUCYNTA™ provided significant relief of moderate to severe acute pain compared to placebo.

PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., will market NUCYNTA™ in the United States.

To see the NUCYNTA™ full prescribing information, go to http://www.pricara.com/pricara/pages/products_list.jsp or www.NUCYNTA.com.

Clinical Studies

Multiple Phase 3 studies presented at the 27th Annual Scientific Meeting of the American Pain Society in May 2008 showed that NUCYNTA™ offered patients significant relief of their pain when compared to placebo, and that the medicine was generally well tolerated in these studies. The studies were published in peer-reviewed journals.

Patients with different pain conditions participated in the NUCYNTA™ Phase 3 clinical studies: those who had a bunionectomy, a standard foot surgery associated with predictable levels of moderate to severe pain, those with pain from end-stage joint disease of the hip or knee, and those with low back pain.

An additional Phase 3 clinical study published in the June 2009 issue of the journal *Current Medical Research and Opinion* found that NUCYNTA™ at 50-mg provided patients with equivalent efficacy in pain relief following orthopedic surgery and significant reduction in composite incidence of nausea and/or vomiting compared to 10-mg of oxycodone IR.

IMPORTANT SAFETY INFORMATION

Like other drugs with mu-opioid agonist activity, NUCYNTA™ is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma or hypercapnia in unmonitored settings or in the absence of resuscitative equipment. NUCYNTA™ is contraindicated in patients who have or are suspected to have paralytic ileus. NUCYNTA™ is also

contraindicated in patients currently using or within 14 days of using monoamine oxidase inhibitors (MAOIs) due to potential additive effects on norepinephrine levels, which may result in adverse cardiovascular events.

Respiratory depression is the primary risk of mu-opioid agonists. Respiratory depression occurs more frequently in elderly or debilitated patients and in those suffering from conditions accompanied by hypoxia, hypercapnia, or upper airway obstruction, in whom even moderate therapeutic doses may significantly decrease pulmonary ventilation. NUCYNTA™ 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. In such patients, even usual therapeutic doses of NUCYNTA™ may increase airway resistance and decrease respiratory drive to the point of apnea. Alternative non-mu-opioid agonist analgesics should be considered and NUCYNTA™ should be employed only under careful medical supervision at the lowest effective dose in such patients. If respiratory depression occurs, it should be treated as any mu-opioid agonist-induced respiratory depression.

Patients receiving other mu-opioid agonist analgesics, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) concomitantly with NUCYNTA™ may exhibit additive CNS depression. Interactive effects resulting in respiratory depression, hypotension, profound sedation, coma or death may result if these drugs are taken in combination with NUCYNTA™. When such combined therapy is contemplated, a dose reduction of one or both agents should be considered.

Opioid analgesics can raise cerebrospinal fluid pressure as a result of respiratory depression with carbon dioxide retention. Therefore, NUCYNTA™ should not be used in patients susceptible to the effects of raised cerebrospinal fluid pressure such as those with head injury and increased intracranial pressure. Opioid analgesics may obscure the clinical course of patients with head injury due to effects on pupillary response and consciousness. NUCYNTA™ should be used with caution in patients with head injury, intracranial lesions, or other sources of preexisting increased intracranial pressure.

NUCYNTA™ is a mu-opioid agonist and is a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. NUCYNTA™ can be abused in a manner similar to other mu-opioid agonists, legal or illicit. This should be considered when prescribing or dispensing NUCYNTA™ in situations where the physician or pharmacist is concerned about an increased risk of misuse and abuse. All patients treated with mu-opioid agonists require careful monitoring for signs of abuse and addiction. NUCYNTA™ may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death.

Experience with NUCYNTA™ overdose is very limited. Management of overdose should be focused on treating symptoms of mu-opioid agonism. Primary attention should be given to reestablishment of a patent airway and institution of assisted or controlled ventilation when overdose of NUCYNTA™ is suspected. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

Patients should be cautioned that NUCYNTA™ may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. This is to be expected especially at the beginning of treatment, at any change of dosage as well as in combination with alcohol or tranquilizers.

NUCYNTA™ has not been systematically evaluated in patients with a seizure disorder, and such patients were excluded from clinical studies. NUCYNTA™ 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 NUCYNTA™, 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). Serotonin syndrome may include mental-status changes (eg, agitation, hallucinations, coma), autonomic instability (eg, tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (eg, hyperreflexia, incoordination) and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea).

Withdrawal symptoms may occur if NUCYNTA™ is discontinued abruptly. These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, piloerection, and rarely, hallucinations. Withdrawal symptoms may be reduced by tapering NUCYNTA™.

Pregnancy Category C. There are no adequate and well-controlled studies of NUCYNTA™ in pregnant women. NUCYNTA™ should be used during pregnancy ONLY if the potential benefit justifies the potential risk to the fetus. NUCYNTA™ is not recommended for use in women during and immediately prior to labor and delivery. Neonates whose mothers have been taking NUCYNTA™ should be monitored for respiratory depression. NUCYNTA™ should not be used during breastfeeding.

NUCYNTA™ is not recommended in patients with severe renal or hepatic impairment. NUCYNTA™ should be used with caution in patients with moderate hepatic impairment. Like other drugs with mu-opioid agonist activity, NUCYNTA™ may cause spasm of the sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis.

The most common adverse events are nausea, dizziness, vomiting, somnolence and headache.

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PriCara® , Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., is a major healthcare 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.

Grünenthal

Grünenthal, a privately owned pharmaceutical company based in Aachen, Germany, discovered and started development of tapentadol. Grünenthal and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. 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 Pharmaceuticals, Inc. for the United States, Canada and Japan. Grünenthal maintains marketing rights in Europe and other parts of the world.

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