PENNSAID(R) Launch Brings New Treatment to Knee Osteoarthritis Patients

Covidien

New NSAID Treatment Now Available for Nearly 10 Million American Knee Pain Sufferers

ST. LOUIS, Apr 26, 2010 (BUSINESS WIRE) --Covidien (NYSE: COV), a leading global provider of healthcare products, has introduced PENNSAID(R) (diclofenac sodium topical solution) 1.5% w/w to the U.S. market. PENNSAID is the only FDA-approved topical non-steroidal anti-inflammatory drug (NSAID) in a vehicle solution containing dimethyl sulfoxide (DMSO), a known penetrating agent. It is indicatedfor treatment of the signs and symptoms of osteoarthritis of the knee(s).

PENNSAID offers patients suffering from osteoarthritis of the knee an effective option for reducing pain and improving physical function.

"We believe PENNSAID will become an important treatment for physicians caring for patients with osteoarthritis of the knee," said Timothy R. Wright, President, Pharmaceuticals, Covidien. "The product's unique formulation with DMSO and its proven clinical effectiveness make it a convenient and innovative treatment for patients who are seeking effective pain relief and improved physical function in their daily lives."

A growing number of guidelines and review committees suggest that the use of topical NSAIDs in the treatment of knee osteoarthritis offers potential significant gastrointestinal safety benefits for certain patients. Localized treatment may provide improved safety and tolerability benefits.

In Phase III clinical trials, PENNSAID demonstrated statistically significant differences in all three primary efficacy endpoints: pain and physical function (as measured by the Western Ontario and McMaster Universities LK3.1 OA Index, or WOMAC subscale), and patient overall health assessment (POHA) / patient global assessment (PGA).[1,2,3]

"Ten million Americans suffer from osteoarthritis of the knee, illustrating the clear need for additional treatment alternatives," said Charles Argoff, M.D., Professor of Neurology at Albany Medical College and Director of the Comprehensive Pain Program of Albany Medical Center. "Though osteoarthritis is not preventable, many people are able to manage it and maintain an active lifestyle with a well designed treatment program, including medications, exercise, and physical therapy when needed."

According to the Arthritis Foundation, moderate exercise provides multiple benefits for people with osteoarthritis - reducing joint pain and stiffness, building strong muscle around the joints and increasing flexibility and endurance for osteoarthritic

patients.[4] Education around appropriate knee osteoarthritis treatment is especially timely, as May is National Arthritis Awareness Month.

Knee osteoarthritis is one of five leading causes of disability among adults[5,6] and is a chronic condition characterized by the breakdown of the joint's cartilage. Cartilage cushions the ends of the bones and allows easy movement of joints. The breakdown of this cartilage causes the bones to rub against each other, resulting in stiffness, pain and loss of movement in the joint.[7]

Symptoms of osteoarthritis include joint pain or stiffness following periods of either inactivity or excessive use, a grating or catching sensation during joint movement and bone spurs (small growth of new bone) in the affected joints.[7]

Last November, Covidien with Nuvo Research announced the U.S. Food and Drug Administration (FDA) had approved the New Drug Application for PENNSAID.

About Covidien

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2009 revenue of $10.7 billion, Covidien has 42,000 employees worldwide in more than 60 countries, and its products are sold in over 140 countries. To learn more about our business, please visit www.covidien.com [1].

About PENNSAID(R)

PENNSAID (diclofenac sodium topical solution) 1.5% w/w is a NSAID in a vehicle solution containing the penetrating agent DMSO.[1,2] PENNSAID was developed to help increase the effective, local delivery of pain relief to patients suffering from knee osteoarthritis, a disorder impacting an estimated 10 million patients in the United States.[8] PENNSAID is the only FDA-approved topical NSAID for the treatment of knee osteoarthritis which demonstrated statistically significant differences in all three primary efficacy endpoints: pain and physical function (WOMAC), patient overall health assessment (POHA) and patient global assessment of knee osteoarthritis.[1,2,3,9]

About Osteoarthritis

Osteoarthritis is a chronic condition characterized by the breakdown of cartilage in the joint. Cartilage cushions the ends of the bones in joints - such as knees, hands, elbows, wrists, ankles and feet - which allows for easy movement. When this cartilage erodes, bones can rub together, resulting in pain and loss of free movement in the joint. Today, an estimated 27 million Americans live with osteoarthritis.[7]

The most common symptoms include pain, joint soreness, stiffness and

deterioration of overall coordination, posture and walking. Despite the high prevalence of osteoarthritis, there is no cure for this disease, which tends to progressively reduce mobility and the overall health state in affected patients.

IMPORTANT RISK INFORMATION ABOUT PENNSAID(R)

Cardiovascular Risk

- **Nonsteroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.**
- **PENNSAID is contraindicated in the perioperative setting of coronary artery bypass graft (CABG) surgery.**

Gastrointestinal Risk

- **NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.**

PENNSAID is contraindicated in patients:

- with a known hypersensitivity to diclofenac sodium or any other component of PENNSAID
- who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal anaphylactic-like reactions to NSAIDs have been reported in such patients.

Elevation of one or more liver tests may occur during therapy with NSAIDs.

PENNSAID should be discontinued immediately if abnormal liver tests persist or worsen.

Use with caution in patients with fluid retention or heart failure. Hypertension can occur with NSAID treatment. Monitor blood pressure closely with PENNSAID treatment.

Long-term administration of NSAIDs can result in renal papillary necrosis and other renal injury. Use PENNSAID with caution in patients at greatest risk of this reaction, including the elderly, those with impaired renal function, heart failure, liver dysfunction, and those taking diuretics and ACE-inhibitors.

Should not be used in pregnant or lactating women and is not approved for use in pediatric patients.

Anaphylactoid reactions may occur in patients without prior exposure to PENNSAID. NSAIDs can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal.

The most common treatment-related adverse events in patients receiving PENNSAID were application site skin reactions including dry skin (32%), contact dermatitis characterized by skin erythema and induration (9%), contact dermatitis with vesicles (2%) and pruritus (4%). In a long term safety study, contact dermatitis occurred in 13% and contact dermatitis with vesicles in 10% of patients, generally within the first 6 months of exposure, leading to a withdrawal rate for an application site event of 14%. Other common adverse events greater than placebo include: dyspepsia (9%), abdominal pain (6%), flatulence (4%), diarrhea (4%) and nausea (4%).

Do not apply to open wounds. Protect treated knee(s) from natural or artificial sunlight. Topicals such as sunscreen and bug repellant may be applied after PENNSAID treated knee(s) are completely dry. Avoid contact of PENNSAID with eyes and mucous membranes. Wash and dry hands after use.

Concurrent use with oral NSAIDs should be avoided unless benefit outweighs risk and periodic laboratory evaluations are conducted.

See Full Prescribing Information [2]**for additional Important Risk Information.**

PENNSAID is a registered trademark of Nuvo Research Inc.

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[2] Roth SH, Shainhouse JZ. Efficacy and safety of a topical diclofenac solution

(PENNSAID) in the treatment of primary osteoarthritis of the knee. *Arch Intern Med*. 2004; 164:2017-2023.

[3] PENNSAID Product Insert. Dosage and administration.

[4] Arthritis Foundation. Osteoarthritis: Treatment Options "Self-Management Techniques, Exercise" http://www.arthritis.org/disease-center.php?disease_id=32&df=treatments [3] [Last Accessed April 2010]

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[6] Guccione AA, Felson DT, Anderson JJ, et al. The effects of specific medical conditions on the functional limitations of elders in the Framingham study. *Am J Public Health.* 1994; 84:351-358. [Last Accessed April 2010]

[7] Arthritis Foundation. Osteoarthritis Fact Sheet. http://www.arthritis.org/media/newsroom/media-kits/Osteoarthritis_fact_sheet.pdf [5] [Last Accessed April 2010]

[8] Parmet, S., Lynm, C., & Glass, R. M. (2003). Osteoarthritis of the Knee. *JAMA*, 289(8), 1068.

[9] Tugwell, P. S., Wells, G. A., & Shainhouse, J. Z. Equivalence study of a topical diclofenac solution (PENNSAID) compared with oral diclofenac in symptomatic treatment of osteoarthritis of the knee: a randomized controlled trial. *Journal of Rheumatology*, 2004;31(10), 2002-12.

SOURCE [6]

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