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COLCRYS® (COLCHICINE, USP) SHOWS SUPERIOR SAFETY WITH COMPARABLE EFFICACY COMPARED TO HIGH-DOSE COLCHICINE IN TREATMENT OF EARLY ACUTE GOUT FLARES

Study Published in April Issue of *Arthritis & Rheumatism*

PHILADELPHIA, March 31, 2010 – A newly-published clinical study demonstrates that Colcrys® (colchicine, USP), a low-dose oral colchicine, is just as effective as high-dose colchicine in reducing pain associated with early acute gout flare, but with a safety profile statistically indistinguishable from placebo.

The study, “High vs. Low-dosing of Oral Colchicine for Early Acute Gout Flare: Twenty-Four Hour Outcome Results of the First Randomized, Placebo-Controlled, Dose Comparison Colchicine Trial,” details the AGREE (**A**cute **G**out Flare **R**eceiving **C**olchicine **E**valuation) trial, the first placebo-controlled comparison of low-dose and high-dose colchicine in the treatment of acute gout flares. The study was published in the April issue of *Arthritis & Rheumatism*, the official journal of the American College of Rheumatology. AGREE formed the basis for URL Pharma’s New Drug Application (NDA) submission for Colcrys to the U.S. Food and Drug Administration (FDA).

“For centuries, colchicine for the indication of acute gouty arthritis has been dosed at levels higher than clinically necessary,” said Robert A. Terkeltaub, M.D., Section Chief, Rheumatology-Allergy, VA Medical Center San Diego, and Professor of Medicine and Rheumatology Training Program Director, University of California San Diego. “This study is the first to demonstrate that a low-dose colchicine regimen is just as effective as a high-dose regimen in the treatment of early gout flare, defined as within 12 hours of symptom onset. The low dose colchicine regimen of only a total 3 tablets of 0.6 mg given over only one hour avoids the significant toxicities traditionally associated with high doses repeated over many hours, in this case a total of 8 tablets of 0.6 mg colchicine given over 6 hours.” Dr. Terkeltaub was the primary investigator and lead author for the AGREE trial.

Colcrys received approval from the FDA on July 30, 2009 for the treatment of acute gout flares at the first sign of a flare, and for the prevention of gout flares on October 19, 2009. Colcrys is the first and only single-ingredient colchicine to receive FDA approval. Other single-ingredient colchicine products currently on the market have never received regulatory review or approval, and have been traditionally used at doses that cause severe toxicities in nearly all patients.

“The approval of Colcrys was based on strong science that included the AGREE trial and 16 additional clinical studies conducted by URL Pharma that determined, for the first time, the appropriate dose and toxicity profile of colchicine for the treatment of gout,” said Richard H. Roberts, M.D., Ph.D., President, CEO and Chairman, URL Pharma. “These studies uncovered serious, potentially life-threatening interactions with commonly used treatments such as hypertension drugs and antibiotics. Our research represents a major therapeutic step forward for patients, and provides important new guidance for physicians on the safe and appropriate use of colchicine.” The FDA has reported on 169 deaths associated with unapproved colchicine.

Study Details

The multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluated the safety and efficacy of low- vs. high-dose colchicine in male and postmenopausal female patients aged ≥ 18 years with a confirmed past diagnosis of gout and ≥ 2 gout flares within the prior 12 months. A stable regimen of urate-lowering therapy was permitted. A total of 575 patients were randomized into one of three treatment groups: 1) a novel "low-dose" abbreviated colchicine regimen (Colcrys) group; 2) a "high-dose" colchicine regimen group that reflects long-standing medical practice and is still actively taught to physicians; 3) placebo. The primary endpoint was $\geq 50\%$ pain reduction at 24 hours without rescue medication.

Among 184 patients in the intent-to-treat population, results at 24 hours demonstrated superior safety of Colcrys, without loss of efficacy, relative to high-dose colchicine for early acute gout flares when self-administered within 12 hours of flare onset. The percent of patients responding to treatment was proportionally greater in the Colcrys group compared to the high-dose and placebo arms across the entire pain improvement range. The overall adverse events (AEs) profile for Colcrys was statistically similar to placebo (36.5% versus 27.1%, respectively). The high dose associated with unapproved colchicine resulted in significantly more adverse events when compared to Colcrys and placebo, including diarrhea (76.9%, 23.0% and 13.6 % respectively), nausea (17.3%, 4.1% and 5.1% respectively) and vomiting (17.3% versus 0% for both Colcrys and placebo). All AEs in the low-dose group were mild to moderate in intensity while 19.2% of the high-dose group had AEs of severe intensity, all of which were diarrhea.

About Gout and Painful Gout Flares

Gout is a painful form of arthritis that affects an estimated 3 to 5 million Americans, most commonly adult men. It occurs when excess uric acid in the body is deposited as needle-like crystals, or tophi, in the joints or soft tissues, which cause inflammatory arthritis and can lead to gout flares typically lasting three to 10 days.

Gout flares are characterized by intermittent swelling, redness, heat, joint stiffness and pain, which are often excruciating and can be debilitating enough to significantly interfere with work, social activities and daily living. For many people, gout initially affects the joint of the big toe, though it can also affect other joint areas such as the ankles, heels, knees, wrists, fingers and elbows.

Important Safety Information

COLCRYS[®] (colchicine, USP) tablets are indicated for prophylaxis and the treatment of gout flares.

COLCRYS is contraindicated in patients with renal or hepatic impairment who are concurrently prescribed P-gp inhibitors or strong inhibitors of CYP3A4 as life-threatening or fatal toxicity has been reported. Dose adjustments of COLCRYS may be required when co-administered with P-gp or CYP3A4 inhibitors. The most common adverse events in clinical trials for the prophylaxis and treatment of gout were diarrhea and pharyngolaryngeal pain. Rarely, myelosuppression, thrombocytopenia, and leukopenia have been reported in patients taking colchicine. Rhabdomyolysis has been occasionally observed, especially when colchicine is prescribed in combination with other drugs known to cause this effect. Monitoring is recommended for patients with a history of blood dyscrasias or rhabdomyolysis.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1.800.FDA.1088.

You may also report negative side effects to the manufacturer of COLCRYS by calling 1.888.351.3786.

Please see www.colcrys.com for full Prescribing Information.

About URL Pharma

URL Pharma, Inc., headquartered in Philadelphia, PA, is a leading specialty pharmaceutical company with fully integrated technology development, product development, manufacturing, and commercialization capabilities. After a long history of generic pharmaceutical research, development, and manufacturing, the Company has successfully transitioned to a technology-driven, specialty pharmaceutical business. The Company seeks to develop and commercialize scientifically and medically innovative products that address unmet medical needs for improvements in safety and efficacy. The Company's profits are derived predominantly from its exclusive products and technologies. For additional information about the company, please visit www.urlpharma.com. For further information, please call 215-697-1900 or media@urlpharma.com.

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