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NEW DATA PRESENTED AT ACR MEETING DEMONSTRATES COLCRYS™ (COLCHICINE, USP) SIGNIFICANTLY REDUCES PAIN OF ACUTE GOUT FLARE WITHIN 24 HOURS WITH SIDE EFFECTS COMPARABLE TO PLACEBO

Studies Confirm Clinical Benefit, Reveal New Information on Safety and Pharmacokinetics of Colcrys

PHILADELPHIA, October 19, 2009 – URL Pharma, Inc., today announced data from a pivotal Phase III study demonstrating that Colcrys™ (colchicine, USP), a low-dose colchicine, reduced the pain of gout flares within a 24-hour period as effectively as high-dose colchicine with a side effect profile statistically indistinguishable from placebo. These data and two other Colcrys studies were presented this week at the 2009 American College of Rheumatology (ACR) Annual Scientific Meeting in Philadelphia.

“These studies confirm that Colcrys offers patients effective relief of gout flares with significantly reduced side effects and a greater margin of safety,” 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. “The data provide critical guidance for physicians on the optimal use of colchicine, and signal a positive change in how we manage acute gout flares.” Dr. Terkeltaub was the primary investigator for the AGREE (Acute Gout Flare Receiving Colchicine Evaluation) study presented at the 2008 ACR Annual Meeting.

Colcrys™ is approved for the prophylaxis and treatment of gout flares. It is the first and only single-agent colchicine treatment to receive FDA approval. Colcrys provides a formulation with the same efficacy of high dose colchicine while avoiding most of the toxicity of the unapproved products currently on the market.

“These clinical studies with colchicine - the first of their kind ever conducted - have resulted in significant benefit and value to patients living with gout,” said Richard H. Roberts, M.D., Ph.D., President, Chief Executive Officer and Chairman of URL Pharma. “The data presented today reaffirm the role of colchicine as a cornerstone therapy in the treatment of gout, provide valuable information on how to dose colchicine while reducing side effects, and highlight potential and previously unknown drug-drug interactions, giving physicians the information they need to prescribe colchicine with greater confidence.”

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Study Design

This Phase III, randomized, double-blind, placebo-controlled, parallel group study represents a secondary analysis of the previously presented AGREE trial data. A total of 184 patients having a clinical diagnosis of gout according to ACR guidelines received either study drug or placebo. Fifty-two patients received high-dose colchicine (1.2 mg, then 0.6 mg hourly x 6 hours = 4.8 mg total); 74 received Colcrys (1.2 mg, then 0.6 mg in 1 hour = 1.8 mg total, followed by 5 placebo doses hourly); and 58 were assigned to placebo (2 capsules, then 1 capsule hourly x 6 hours).

The study's primary endpoint was a 50 percent reduction in joint pain at 24 hours post first dose. Researchers also compared pain improvement scores at 24 and 32 hours after the first dose. Patients recorded pain intensity (as measured by a 0-10 point Likert pain scale) and adverse events over 72 hours.

Study Results

In this analysis, 43.2 percent of patients experienced a 2 point or greater reduction in pain on the Likert scale 24 hours after taking Colcrys compared with 17.2 percent in the placebo group ($p = 0.0015$). The therapeutic effect was sustained at 32 hours post-Colcrys dosing, with 45.9 percent of Colcrys patients experiencing a 2 point or greater reduction in pain versus 17.2 percent in the placebo group ($p = 0.0005$). While the Colcrys and high-dose colchicine groups experienced similar pain relief at 24 and 32 hours, the safety profile of Colcrys was significantly improved over high-dose colchicine. The rate of adverse events seen in the Colcrys-treated patients was comparable to placebo.

Additional Colcrys Studies

Two additional studies provide new data on the concomitant dosing of colchicine with the calcium channel blocker verapamil and additional evidence of the safety of Colcrys™ dosing in the treatment of gout flares.

Verapamil Drug Interaction Study

Researchers presented a Phase I study assessing the effect of verapamil on the pharmacokinetics of single-dose colchicine, the first time this commonly-prescribed hypertension medication has been evaluated for interactions with colchicine. Hypertension is one of many co-morbid conditions often experienced by gout patients, so an understanding of interactions with drugs often used in conjunction with colchicine is of critical importance to physicians.

This open-label, 2-period, drug-drug interaction (DDI) study examined 24 fasting subjects, who received a single 0.6-mg oral dose of colchicine on Day 1. Blood samples were drawn at various times for pharmacokinetic (PK) analysis on Days 2-5. After a 10-day washout period, subjects received 240 mg verapamil once daily for five days. On day 19, a second colchicine dose (0.6 mg) was given. Blood samples were drawn for PK analysis on Days 20-23.

The study demonstrated that verapamil increases colchicine concentrations in the blood by 30 percent. The researchers concluded that, for the treatment of acute gout flare, the standard dose of colchicine should be reduced from 3 to 2 tablets for patients on verapamil or diltiazem. Colchicine dosing should be reduced by 50 percent when administered chronically and concomitantly with verapamil or diltiazem (another calcium channel blocker previously studied by URL Pharma for drug-drug interactions).

Pharmacokinetic dosing of colchicine

Investigators presented a Phase I study of 75 healthy volunteers evaluating the pharmacokinetics of Colcrys as single dose, low-dose and high-dose regimens. Plasma samples were collected following single-dose (0.6mg, both after food and while fasting), low dose (1.2 mg + 0.6 mg after 1 hour) and high-dose (1.2 mg + 0.6 mg x6) Colcrys regimens. Adverse events were assessed and cardiac safety was measured by ECG.

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Results showed that high-dose and low-dose regimens of Colcrys had similar steady-state plasma concentrations and blood levels. However, the high-dose regimen showed a two-fold greater total exposure when compared with the low-dose regimen. The analysis suggested that peak colchicine blood levels of about 6 ng/mL are adequate for pain reduction in the first 24 hours after a gout flare. The investigators concluded that additional exposure from high-dose colchicine may only increase unwanted side effects, and recommended low-dose Colcrys (1.2 mg + 0.6 mg after 1 hr) for early acute gout flare treatment. The most common adverse events in this study were headache, diarrhea, dizziness, nausea, stomach pain, and vomiting. All were mild-to-moderate and did not result in discontinuation.

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 the prophylaxis and treatment of acute gout flares in adults.

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. 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 profitable, 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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