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## FDA APPROVES COLCRYST™ (COLCHICINE, USP) FOR PREVENTION OF GOUT FLARES

*New Colchicine Formulation Significantly Reduces Side Effects, Maintains Full Efficacy;  
Now Indicated for Both Prophylaxis and Treatment of Gout Flares*

**PHILADELPHIA, October 19, 2009** – URL Pharma, Inc., today announced that the U.S. Food and Drug Administration (FDA) has approved Colcrys™ (colchicine, USP) for the prophylaxis (prevention) of gout flares. Colcrys was first approved by the FDA on July 30, 2009 for the treatment of acute gout flares when taken at the first sign of a flare.

Colcrys is an oral, branded form of colchicine that has been formulated for optimal efficacy and tolerability. It is the only single-ingredient colchicine to be approved by the FDA for the prophylaxis and treatment of gout flares. Colcrys provides a formulation with the efficacy of colchicine while avoiding most of the toxicity of the unapproved products historically on the market. Colcrys is also indicated for the treatment of Familial Mediterranean Fever (FMF) in adults and children 4 years of age or older. Colcrys is available via prescription at pharmacies nationwide.

“With the FDA’s approval of Colcrys for the prevention of gout flares, patients and physicians will now be able to realize the full therapeutic potential of Colcrys as a cornerstone therapy in the management of gout,” said Richard H. Roberts, M.D., Ph.D., President, CEO and Chairman, URL Pharma. “Our clinical research on colchicine – the first of its kind ever conducted -- has brought colchicine manufacturing, dosing, safety and efficacy information into compliance with current FDA standards.”

Two randomized clinical trials assessed the efficacy of colchicine 0.6 mg twice a day for the prophylaxis of gout flares in patients initiating treatment with uric-acid lowering therapy. In both trials, treatment with colchicine decreased the frequency of gout flares. Colchicine has been shown to be well-tolerated when paired with uric acid-lowering agents such as allopurinol. The dosing of Colcrys for gout flare prophylaxis is one tablet (0.6 mg) once or twice a day. The maximum daily dose for prophylaxis is two tablets (1.2 mg).

“Uric acid-lowering agents are highly effective and well-established in chronic gout management, but the initiation of this therapy may sometimes trigger a gout flare,” said Matthew W. Davis, M.D., R.Ph., Vice President, Branded Products and Medical Affairs, URL Pharma. “Colchicine has been proven to be effective in preventing flares when given in conjunction with uric acid-lowering therapy, and with Colcrys, doctors can now prescribe colchicine with greater confidence.”

The most commonly reported adverse reaction in clinical trials of colchicine for the prophylaxis of gout was diarrhea. In the presence of mild-to-moderate renal or hepatic impairment, adjustment of dosing is not required for use in gout flare prophylaxis, but

patients should be monitored closely for adverse effects of colchicine. In patients with severe renal impairment, the starting dose for prophylaxis of gout flares should be 0.3 mg per day and any increase in dose should be done with close monitoring. For patients undergoing dialysis, the total recommended dose for prophylaxis of gout flares should be 0.3 mg given twice a week with close monitoring. In patients with severe hepatic impairment, a dose reduction may be needed in prophylaxis of gout flares. Full prescribing information can be found at [www.colcrys.com](http://www.colcrys.com).

URL Pharma is establishing a Patient Assistance Program (PAP) for patients with limited means who may require assistance in obtaining Colcrys. The program is expected to launch in the fourth quarter of 2009. Once the program has been established, patients may visit [www.colcrys.com](http://www.colcrys.com) or [www.urlpharma.com](http://www.urlpharma.com) for more information.

### **Colchicine in Gout Treatment**

Colchicine has been utilized as a treatment for gout for centuries. However, unapproved colchicine has not been reviewed by the FDA for safety and efficacy. As a result, critical information about unapproved colchicine products -- including safety and efficacy, potential adverse events, drug interactions and manufacturing practices -- cannot be determined. The FDA has undertaken an initiative to bring unapproved, marketed products like colchicine under its regulatory framework. This initiative promotes the goal of assuring that all marketed drugs meet modern standards for safety, effectiveness, quality and labeling. The FDA has the authority to remove unapproved colchicine from the market. More information is available at [www.fda.gov/Drugs/DrugSafety](http://www.fda.gov/Drugs/DrugSafety).

### **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.

### **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](http://www.urlpharma.com). For further information, please contact us at 215-697-1900 or [media@urlpharma.com](mailto:media@urlpharma.com).

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