



Newly Published Data Shows Kristalose Preferred by 77% More Patients Compared to Liquid Lactulose

-- Patients with chronic constipation prefer taste, consistency and portability of Kristalose

NASHVILLE, Tenn., Dec. 1, 2010 /PRNewswire-FirstCall/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced the publication of a patient preference study evaluating Kristalose® (*lactulose*) for Oral Solution, a prescription laxative packaged as a crystalline powder, compared to liquid lactulose products. The study, which appeared in the Volume 3, 2010 issue of *Clinical and Experimental Gastroenterology*, showed that patients with chronic constipation preferred the taste, consistency and portability of Kristalose over similar products in liquid forms.

Chronic constipation affects an estimated 15 percent of the North American population(1) and can result in serious discomfort, decreased quality of life and hospitalization.(2) Research shows that lactulose, which is available in both a powder and liquid formulation, is an effective treatment that consistently relieves constipation.(3)

"This preference for Kristalose over liquid syrups due to taste as well as the convenience of pre-measured powder packets could translate into patients being more likely to take their constipation medication as directed," said Charles F. Barish, M.D., lead author of the publication, President of Wake Research Associates in Raleigh, North Carolina, and Clinical Assistant Professor of Medicine at the University of North Carolina School of Medicine. "Patient preference often correlates with enhanced compliance, which can affect clinical outcomes."

The prospective, randomized, open-label, multicenter study evaluated 50 adult patients with a recent diagnosis of chronic constipation to measure overall preference between powder and liquid lactulose as well as preference in terms of taste, consistency and portability. The two-week study also measured the occurrence of adverse events. Patients were randomized to receive powder or liquid lactulose for seven days. The patients then crossed over to the alternative treatment for the following seven days. Doses of both formulations were determined by the patient's treating physician and patient preference was assessed by questionnaire.

More than six times as many patients preferred the portability of powder compared with liquid lactulose. Of patients expressing a preference, 44% and 57% more patients preferred the taste and consistency, respectively, of Kristalose over liquid lactulose. Overall, 77% more patients preferred Kristalose over liquid lactulose. There was no significant difference in adverse events between patients who took Kristalose and those taking liquid lactulose.

"These findings affirm our long-held belief that the unique packaging of Kristalose in pre-dosed powder packets offers distinct benefits to patients, which can enhance ease-of-use and, ultimately, influence outcomes," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are pleased to offer a product that is not only safe and effective, but also offers advantages in the areas of taste, consistency and portability."

Kristalose is a proprietary prescription laxative and unique crystalline form of lactulose that treats acute and chronic constipation. The drug dissolves quickly in four ounces of water, offering patients a virtually tasteless and grit-free alternative to other liquid lactulose treatments. There are no age limitations or length of use restrictions for Kristalose, and it is the only osmotic prescription laxative still sampled to physicians.

The study, entitled "Comparison of preference and safety of powder and liquid lactulose in adult patients with chronic constipation," can be found online at <http://www.dovepress.com/comparison-of-preference-and-safety-of-powder-and-liquid-lactulose-in-peer-reviewed-article-CEG>.

About Kristalose

Kristalose® (*lactulose*) for Oral Solution is indicated for the treatment of acute and chronic constipation. It is a unique, proprietary, crystalline form of lactulose, with no restrictions on length of therapy or patient age. Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia and hypernatremia. Nausea and vomiting have been reported. Use with caution in diabetics. Kristalose is contraindicated in patients who require a low-galactose diet. Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically. For full prescribing information, visit www.kristalose.com.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's product portfolio includes Acetadote® (acetylcysteine) Injection for the treatment of acetaminophen poisoning, Caldolor® (ibuprofen) Injection, the first injectable treatment for pain and fever available in the United States, and Kristalose® (lactulose) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, please visit the Company's website at www.cumberlandpharma.com.

About Clinical and Experimental Gastroenterology

Clinical and Experimental Gastroenterology is an international, peer-reviewed, open access, online journal publishing original research, reports, editorials, reviews and commentaries on all aspects of gastroenterology in the clinic and laboratory.

Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that reflect Cumberland's current views with respect to future events, based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include, among other things, market conditions, competition from existing and new products, an inability of manufacturers to produce the Company's products on a timely basis or a failure of manufacturers to comply with stringent regulations applicable to pharmaceutical drug manufacturers, maintaining and building an effective sales and marketing infrastructure, government regulation, the possibility that marketing exclusivity and patent rights may provide only limited protection from competition, and other factors related to the Company, including those set forth under the headings "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" in Cumberland's Form 10-K filed with the SEC on March 19, 2010. There can be no assurance that the results or developments anticipated by Cumberland will be realized or, even if substantially realized, that they will have the expected effects. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cumberland undertakes no obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

(1) Gallagher P, O'Mahony D. Constipation in old age. *Best Pract Res Clin Gastroenterol*. 2009; 23 (6): 875-887.

(2) Johanson JF, Kralstein J. Chronic constipation: A survey of the patient perspective. *Ailment Pharmacol Ther*. 2007; 25 (5): 599-608.

(3) American College of Gastroenterology Chronic Constipation Task Force. An evidence-based approach to the management of chronic constipation in North America. *Am J Gastroenterol*. 2005; 100 Suppl 1: S1-S4.

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