

# News Release

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**Prasco and Takeda Enter into Agreement to Market  
Authorized Generic of Colcris<sup>®</sup> (colchicine, USP) in the United States**  
Companies Committed to Providing Access to Colchicine Tablets

**Cincinnati, OH, Deerfield, Ill., January 12, 2015 and Osaka, Japan, January 13, 2015** — Prasco Laboratories (“Prasco”), Takeda Pharmaceutical Company Limited (“Takeda”), and Takeda’s wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc. (“TPUSA”) announced today that Prasco and TPUSA have entered into a distribution and supply agreement for the rights to distribute Colchicine Tablets, USP, the Authorized Generic (AG) version of Colcris<sup>®</sup> (colchicine, USP) Tablets in the U.S. As a result of this partnership, Colchicine Tablets, USP will be the only colchicine product on the market that is therapeutically equivalent and automatically substitutable for prescriptions written for Colcris Tablets, indicated for the prophylaxis and treatment of acute gout flares in adults, and the treatment of familial Mediterranean fever (FMF) in adults and children age four or older.<sup>1</sup>

Colchicine Tablets, USP will be marketed under the Prasco label and will be widely available in U.S. pharmacies beginning later this week.

“Introducing an Authorized Generic of Colcris provides patients, pharmacists, and physicians with access to a therapeutically equivalent option to Colcris Tablets for the prevention and treatment of gout flares,” stated Prasco chief executive officer, Chris Arington.

“We are certainly pleased to partner with Takeda, an established leader in providing gout treatment options, to make an Authorized Generic of Colcris widely available,” said Jonathan Lapps, Prasco’s senior vice president, business development.

As the leader in the Authorized Generics business, Prasco has now brought more than 65 AG products to market since 2004 and has more AG partners than any other company in the U.S. Authorized Generic products can benefit multiple members of the marketplace by helping enhance access to treatment options.

“At Takeda, we remain committed to providing patients with therapies that are safe, efficacious and meet high quality standards,” said Douglas Cole, president, Takeda Pharmaceuticals U.S.A., Inc. “This new partnership will help enhance patient access to an important gout medicine by supplying Prasco with Colchicine Tablets, USP, manufactured under the same rigorous standards and processes as Colcris.”

Gout affects an estimated 8.3 million Americans, and the prevalence is rising.<sup>2</sup> Colcrys is part of Takeda's gout treatment portfolio, and was launched commercially in the U.S. in 2009. Colcrys is a prescription medicine and was the first FDA-approved single-ingredient oral colchicine product available in the U.S.<sup>3</sup>

### **About Colcrys**

Colcrys (colchicine, USP) 0.6 mg tablet is a prescription medicine used in adults to prevent and treat gout flares. Colcrys is not a pain medicine and should not be taken to treat pain related to other conditions. Colcrys® is a trademark of Takeda Pharmaceuticals U.S.A., Inc. registered with the U.S. Patent and Trademark Office and used under license by Takeda Pharmaceuticals America, Inc.

### **Important Safety Information**

COLCRYS can cause serious side effects or death if levels of COLCRYS are too high in your body. Taking certain medicines with COLCRYS can cause your level of COLCRYS to be too high, even at recommended doses, especially if you have kidney or liver problems. Tell your healthcare provider about all your medical conditions and all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements, and if you consume grapefruit juice. Fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine. Keep COLCRYS out of the reach of children. COLCRYS can also cause serious muscle problems and blood disorders even when taken as directed. You have a higher chance for muscle problems if you are elderly, are taking certain other medicines with COLCRYS, or have kidney problems. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. The most common side effects in people who have gout flares are diarrhea (23%) and throat pain (3%).

For further information, patients should speak with their healthcare provider and see the complete Prescribing Information and Medication Guide for COLCRYS. Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

### **About Prasco Laboratories**

Prasco, the Authorized Generic Company, is a privately held healthcare company located in Mason, Ohio. As the acknowledged category leader, Prasco has more Authorized Generic partnerships than any other company. Established brand companies rely on Prasco to bring their brand products to the generic marketplace as Authorized Generics, which offers alternatives to consumers and pharmacists. For more information, visit [prasco.com](http://prasco.com).

### **About Takeda Pharmaceutical Company Limited**

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com).

## **About Takeda Pharmaceuticals U.S.A., Inc.**

Based in Deerfield, Ill., Takeda Pharmaceuticals U.S.A., Inc. is a subsidiary of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. TPUSA markets oral diabetes, CNS, rheumatology and gastroenterology treatments. Its pipeline includes compounds for metabolic and cardiovascular disease, gastroenterology, neurology and other conditions. To learn more, visit <http://www.takeda.us>.

*This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.*

*Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the United States and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.*

*The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.*

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<sup>1</sup> COLCRYS (colchicine, USP) Prescribing Information. Takeda Pharmaceuticals.

<sup>2</sup> Zhu Y, Pandya BJ, Choi HK. Prevalence of gout and hyperuricemia in the US general population: the National Health and Nutrition Examination Survey 2007-2008. *Arthritis Rheum.* 2011;63:3136-3141.

<sup>3</sup> U.S. Food and Drug Administration. FDA orders halt to marketing of unapproved single-ingredient oral colchicine. September 30, 2010. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm227796.htm>.