



# News Release

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## **Takeda Update Regarding Colcrlys Litigation**

**Deerfield, Ill., January 12, 2015 and Osaka, Japan, January 13, 2015** – Takeda Pharmaceutical Company Limited (“Takeda”) and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc. (TPUSA) stated today that TPUSA will continue its patent infringement litigation against Hikma Pharmaceuticals (“Hikma”) and its lawsuit against the U.S. Food and Drug Administration (FDA) despite two recent court rulings that allowed Hikma to launch its colchicine product.

“We remain committed to pursuing our patent infringement lawsuit against Hikma,” said Kenneth D. Greisman, senior vice president and general counsel, Takeda Pharmaceuticals U.S.A., Inc. “We also believe that the FDA inappropriately approved Hikma’s product and we will continue to challenge that approval.”

On January 9, 2015, the United States Court of Appeals for the Federal Circuit upheld an earlier decision by the United States District Court for the District of Delaware that affirmed the denial of Takeda’s request for a preliminary injunction. The requested injunction would have prohibited the sale of Hikma’s colchicine product during the pendency of Takeda’s patent infringement litigation against Hikma. Colcrlys® (colchicine, USP) is sold by TPUSA and is protected by patents that extend through 2028 and 2029. A trial date in the patent case has not been set.

“Although the trial and appellate courts have not given Takeda preliminary relief, we remain confident that after a trial, Takeda will prevail,” Greisman said.

Also on January 9, 2015, the United States District Court for the District of Columbia denied Takeda’s request to overturn the FDA approval of Hikma’s product. Takeda intends to appeal.

Gout affects more than 8 million Americans, and the prevalence is rising. Colcrlys is part of Takeda’s gout treatment portfolio, and was launched commercially in the U.S. in 2009. Colcrlys is a prescription medicine and was the first FDA-approved single-ingredient oral colchicine product available in the U.S.

## **About Colcrlys**

Colcrlys (colchicine, USP) 0.6 mg tablet is a prescription medicine used in adults to prevent and treat gout flares. Colcrlys is not a pain medicine and should not be taken to treat pain related to other conditions. Colcrlys® 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 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 [www.takeda.us](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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**Contacts:**

Takeda Pharmaceuticals U.S.A., Inc.

Monica Gupta

+1-224-554-2021

Monica.gupta@takeda.com

Takeda Pharmaceutical Company Limited

Corporate Communications Dept.

+81-3-3278-2037