



Imprimis Pharmaceuticals Begins Dispensing Lower Cost Alternative to Thiola®

May 2, 2016

SAN DIEGO, May 2, 2016 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), a pharmaceutical company focused on the development and commercialization of proprietary and customizable drug formulations, today announced the availability of the company's new patent-pending customizable delayed-release (DR) tiopronin formulations as a lower-cost therapeutic alternative to FDA-approved Thiola®. [Thiola](#), FDA-approved as a 100mg tablet, is composed of tiopronin as its sole active drug ingredient and is commonly prescribed for the prevention of cystine kidney stone formation in patients who do not respond to dietary changes and increased fluids. Physicians and their cystinuria patients may now choose from one of two lower-cost compounded alternatives to Thiola.



The company offers two customizable compounded choices:

- Tiopronin DR, which is comprised of the active ingredient tiopronin along with a cellulose-based FDA-approved delayed release agent. This formulation is available in various customizable doses including 200mg and 250mg capsules.
- Tiopronin-K DR is comprised of the active ingredient tiopronin along with potassium citrate in a delayed release capsule, for those patients who have had their potassium citrate dosing titrated. Potassium citrate is the [first-line alkalinizing drug](#) for the treatment of cystinuria. According to the National Organization for Rare Disorders, in addition to chelating medications such as tiopronin, [potassium citrate](#) is often co-prescribed and taken separately to make the urine more alkaline, potentially reducing cystine crystallization and stone formation.

Imprimis' tiopronin compounded formulations may not only significantly lower the cost of cystinuria treatments but also allow patients, for the first time, to reduce the number of pills they consume on a daily basis for this chronic genetic disease. Imprimis' exclusive NDC code for tiopronin should allow patients and their insurance companies to experience a reduction of at least 60% in costs compared to the FDA-approved Thiola per 100mg dose. Many health insurance plans cover compounded drugs and patients not covered will benefit from the *Imprimis Cares* patient access program. Finally, many insurance companies and pharmacy benefit managers have developed or are developing programs to provide patients with lower-cost alternatives to certain FDA-approved branded and generic drugs.

Commitment to Patient Access

Imprimis is committed to the company's mission, vision and values of providing patients with affordable access to the medications they need. As with the company's other lower-cost compounded alternatives, this new alternative to Thiola resulted from the needs of patients, physicians and payors. Significant increases in drug prices, coupled with an increasing number of higher deductible drug benefit plans and some insurance companies simply refusing to cover the costs altogether, are making it difficult for many patients to gain affordable access to the medications they need. Imprimis plans to continue to expand its *Imprimis Cares* formulary and introduce additional drug formulations for patient populations that may not have available alternatives to increasingly expensive FDA-approved medications.

Commitment to Quality

Imprimis is committed to providing high quality medications compounded at FDA-inspected and PCAB-accredited facilities. All active drug ingredients used as components of the formulations are FDA-approved and manufactured to a USP Monograph or a similarly accepted national or international standard. Federal and state oversight is a part of every aspect of the Imprimis drug

supply chain from raw material acquisition to production, testing and dispensing. We strive to meet and/or exceed all quality standards for the formulations we dispense and are committed to transparency to our customers when it comes to batch and lot testing performed, including providing sterility test results for each order we dispense for sterile compounded drugs.

How to Order:

- Cystinuria patients or prescribing physicians, please dial toll free: **(866) 551-7195**
- Order forms are available at <http://imprimiscares.com/formulations/>

Mark L. Baum, CEO of Imprimis, stated, "Cystinuria patients regularly complain about the number of pills they have to take each day and the cost of tiopronin, branded as FDA-approved Thiola, which is the gold standard drug used to treat this chronic genetic disease. Because of the price increase following Retrophin's acquisition of Thiola, some insurance companies no longer cover Thiola. As a result, some patients have been switched to other treatments such as the off-label use of Captopril®, an FDA-approved drug for hypertension and heart failure. Some patients make trips to Canada for Cuprimine® (penicillamine) as an alternative to Thiola. They travel to Canada for Cuprimine because it also experienced a significant price increase when Valeant Pharmaceuticals [raised the price](#) from \$888 to \$26,189, an increase of almost 2,850 percent. Unfortunately, approximately [50 percent of all patients](#) taking penicillamine experience adverse reactions and have to stop taking the medication. The bottom line is that the cystinuria community needs access to affordable supplies of tiopronin and that is exactly what we are making available."

Mr. Baum continued, "Most cystinuria patients require approximately 1,000mg of tiopronin daily. This equates to taking 10 tablets of 100mg Thiola each day. Before we entered the market, physicians, patients, insurance companies, and other healthcare institutions faced a choice - to pay the owner of the FDA-approved medicine the price they desired and in many cases take 10 or more of their tablets a day or switch to an alternative drug that may not work as well. That has changed. The cystinuria community now has an alternative – a new therapeutic choice and a new lower-cost source for tiopronin."

About Cystinuria and Thiola®

[Cystinuria](#) is an inherited disease that causes stones made of the amino acid cystine to form in the kidneys, bladder and/or urethra. There are an estimated 10,000 to 12,000 patients in the U.S. who suffer from this chronic condition and [4,000 to 5,000 of them may be candidates for Thiola](#). In 2014, Retrophin LLC and its CEO at the time, Martin Shkreli, acquired the licensing rights of Thiola from Mission Pharmacal Company and increased the price of Thiola 2,000% from [\\$1.50 per tablet to \\$30 per tablet](#), resulting in cystinuria patients having to grapple with their treatment costs which may exceed more than an estimated [\\$100,000 per year](#). Since Mr. Shkreli's departure from Retrophin, the high price of Thiola remains intact.

About the *Imprimis Cares*™ Program

The *Imprimis Cares* program and its team of compounding pharmacists will work with physicians and their patients to ensure they have affordable access to the medicines they need by compounding customizable therapeutic alternatives using the over 7,800 FDA-approved drugs as components. The *Imprimis Cares* program, available in all 50 states, will work with all third party insurers, pharmacy benefit managers and buying groups to offer its patient-specific customizable compounded drug formulations at affordable prices that ensure accessibility. For more information, please visit www.ImprimisCares.com.

Imprimis is reviewing partnership opportunities to clinically develop additional proprietary formulations under its *Imprimis Cares* program for patient populations that may not have available alternatives to increasingly expensive FDA-approved medications. Interested insurance companies, pharmacy benefit managers (PBMs), physicians, patients, and other interested parties may request information regarding the company's new tiopronin DR compounded formulations and other *Imprimis Cares* formulations at <http://imprimiscares.com/contact/> or contact Gary Seelhorst, Vice President of Business Development at gseelhorst@imprimispharma.com.

About Imprimis Pharmaceuticals

Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a national leader in the development, production and dispensing of novel compounded pharmaceuticals. The company's two business programs, *Imprimis Cares*™ and *Custom Compounding Choice*™, focus on patient outcomes and affordability by offering high quality custom compounded drugs in all 50 states. Headquartered in San Diego, California, Imprimis owns and operates four dispensing facilities located in California, Texas, New Jersey and Pennsylvania. For more information about Imprimis, please visit the company's corporate website at www.ImprimisPharma.com.

Imprimis compounded formulations are not FDA approved and may only be prescribed pursuant to a physician prescription for an individually identified patient consistent with federal and state laws governing compounded drug formulations.

Thiola® is a registered trademark of Mission Pharmacal Company. Imprimis is not affiliated with Mission Pharmacal Company nor Thiola®. Thiola® is an FDA-approved drug. Please consult with your physician regarding which prescription options are most suitable for your specific needs.

Cuprimine® is a registered trademark of Valeant Pharmaceuticals International, Inc. or its affiliates. Imprimis is not affiliated with Valeant Pharmaceuticals International, Inc. or Cuprimine®. Cuprimine® is an FDA-approved drug. Please consult with your physician regarding which prescription options are most suitable for your specific needs.

Capoten® is a registered trademark of Par Pharmaceutical, Inc. Imprimis is not affiliated with Par Pharmaceutical, Inc. Capoten® is an FDA-approved drug. Please consult with your physician regarding which prescription options are most suitable for your specific needs.

SAFE HARBOR

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