



**NEWS RELEASE**

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**Astellas and XenoPort Announce Approval of *Regnite*<sup>®</sup> Tablets for Restless Legs Syndrome in Japan**

*XenoPort to Receive \$10 Million Milestone Payment*

**TOKYO, JAPAN and SANTA CLARA, CA** — January 17, 2012 — Astellas Pharma Inc. (Tokyo: 4503) and XenoPort, Inc. (NASDAQ: XNPT) announced today that *Regnite*<sup>®</sup> (gabapentin enacarbil) has received marketing approval in Japan for the treatment of moderate-to-severe primary restless legs syndrome (RLS).

Ronald W. Barrett, Ph.D., chief executive officer of XenoPort, stated, "We are very pleased that *Regnite* has been approved in Japan. We believe that *Regnite* can offer treatment benefits to RLS patients whose condition is severe enough to need medical treatment. We thank Astellas for all of its efforts to make *Regnite* available to RLS patients in Japan."

The New Drug Application (NDA) filing for *Regnite* employed a bridging strategy based on data supporting safety and efficacy from the successful Phase 2 study in RLS patients and long-term safety study conducted by Astellas in Japan, as well as the RLS clinical program conducted by XenoPort in the United States and supporting pharmacokinetic studies conducted by XenoPort in Japanese subjects. Each of the efficacy studies showed that treatment with *Regnite* was associated with improvement in the International Restless Legs Syndrome rating scale score compared to placebo. Improvement over placebo was also observed on the investigator-rated clinical global impression of improvement scale. The most commonly reported adverse events for *Regnite* were somnolence and dizziness, which were generally transient and mild to moderate in severity.

Yoshihiko Hatanaka, president & chief executive officer of Astellas, said, "Astellas expects to provide an additional option for RLS therapy by introducing *Regnite*, which has a different type of mechanism of action than the existing therapy for RLS in Japan."

**About *Regnite***

Discovered by XenoPort, *Regnite* (gabapentin enacarbil) is dosed once-daily and delivers a new chemical entity that utilizes naturally-occurring, high-capacity nutrient transporters in the gastrointestinal tract to achieve efficient absorption into the body. Once absorbed, *Regnite* is rapidly converted into gabapentin, a compound thought to work by binding to certain calcium channels in the central and peripheral nervous system. *Regnite* provides dose-proportional and extended exposure of gabapentin.

## **About Restless Legs Syndrome**

Restless legs syndrome is a neurological condition that is characterized by unpleasant and sometimes painful sensations in the legs that result in a compelling urge to move and can result in distressing symptoms that disrupt sleep and significantly impact daily activities. These restless legs syndrome-related symptoms typically begin or worsen during periods of rest or inactivity, particularly when lying down or sitting, and may be temporarily relieved by movement. It is estimated that approximately 2.1 million people in Japan suffer from RLS.

## **Astellas/XenoPort Collaboration Arrangement**

In 2005, Astellas obtained exclusive rights to develop and commercialize *Regnite* in Japan, Korea, the Philippines, Indonesia, Thailand and Taiwan. XenoPort has received payments of \$55 million to date under the collaboration agreement. The approval of *Regnite* in Japan entitles XenoPort to an additional milestone payment of \$10 million. XenoPort is eligible to receive potential additional clinical and regulatory milestone payments totaling up to \$20 million. Under the agreement, XenoPort is also eligible to receive royalties on net sales of *Regnite* in the Astellas territory at a royalty rate in the mid-teens on a percentage basis.

## **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 16,800 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology including Transplantation and Infectious Diseases, Oncology, Neuroscience and Diabetes Mellitus (DM) Complications and Metabolic Diseases. For more information on Astellas Pharma Inc., please visit the company Website at [www.astellas.com/en](http://www.astellas.com/en).

## **About XenoPort**

XenoPort is a biopharmaceutical company focused on developing and commercializing a portfolio of internally discovered product candidates for the potential treatment of neurological disorders. HORIZANT<sup>®</sup> (gabapentin enacarbil) Extended-Release Tablets is XenoPort's first Food and Drug Administration-approved product. GlaxoSmithKline holds commercialization rights and certain development rights for gabapentin enacarbil in the United States. *Regnite* (gabapentin enacarbil) was developed in partnership with Astellas Pharma Inc. for the treatment of RLS in Japan. XenoPort holds all other worldwide rights and has co-promotion and certain development rights to gabapentin enacarbil in the United States. XenoPort's pipeline of product candidates includes potential treatments for patients with neuropathic pain, spasticity and Parkinson's disease.

To learn more about XenoPort, please visit the company Website at [www.XenoPort.com](http://www.XenoPort.com).

## **Forward-Looking Statements**

This press release contains "forward-looking" statements, including, without limitation, all statements related to XenoPort's and Astellas' commercialization and marketing of *Regnite* and the timing thereof; the therapeutic and commercial potential of *Regnite*; and potential milestone payments and royalties and the timing thereof. Any statements contained in this press release that are not statements of historical fact may be deemed

to be forward-looking statements. Words such as “believe,” “expects,” “may,” “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon XenoPort's current expectations. Forward-looking statements involve risks and uncertainties. XenoPort's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to Astellas' ability to successfully commercialize and promote *Regnite* in Japan; XenoPort's dependence on its current and additional collaborative partners; and the uncertain therapeutic and commercial value of XenoPort's compounds. These and other risk factors are discussed under the heading “Risk Factors” in XenoPort's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, filed with the Securities and Exchange Commission on November 4, 2011. XenoPort expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

*XenoPort* is a registered trademark of XenoPort, Inc.  
HORIZANT is a registered trademark of GlaxoSmithKline.  
*Regnite* is a registered trademark of Astellas Pharma Inc.

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