



FOR IMMEDIATE RELEASE

# Reckitt Benckiser Pharmaceuticals and XenoPort Enter Into Global Licensing Agreement for Arbaclofen Placarbil

Reckitt Benckiser Pharmaceuticals Plans to Initiate Phase II Trial of Novel Product Candidate as Potential Treatment for Alcohol Use Disorders

RICHMOND, Va. and SANTA CLARA, Calif. (May 15, 2014) — Reckitt Benckiser Pharmaceuticals Inc. and XenoPort, Inc. (NASDAQ: XNPT) announced today that they have entered into a license agreement pursuant to which Reckitt Benckiser Pharmaceuticals will be granted exclusive worldwide rights for the development and commercialization of XenoPort's clinical-stage oral product candidate arbaclofen placarbil for all indications. Arbaclofen placarbil is a patent protected new chemical entity that Reckitt Benckiser Pharmaceuticals plans to advance into a Phase IIB proof-of-concept study for the treatment of alcohol use disorders — a condition affecting more than 140 million people worldwide.<sup>1,2</sup>

Alcohol use disorders are a global public health issue,<sup>2</sup> with an annual economic burden of \$224 billion in the United States alone.<sup>3</sup> Alcoholism is directly responsible for more than 2.5 million deaths each year and is a causal factor in over 60 other major types of disease.<sup>2</sup> The current treatment approach is predominantly psychosocial support and is largely non-medicalized.<sup>4</sup> The majority of healthcare professionals feel underequipped to manage patients with substance abuse – including alcoholism – based on currently available standards of care.<sup>4</sup>

"Reckitt Benckiser Pharmaceuticals recognizes that there is a tremendous need for more effective, well-tolerated treatment options among the growing patient population with alcohol use disorders, and we believe arbaclofen placarbil is a natural fit for our growing addiction treatment pipeline," said Shaun Thaxter, CEO, Reckitt Benckiser Pharmaceuticals Inc. "Over the past decade, we have demonstrated our leadership in the challenging addiction space by helping patients struggling with the chronic disease of opioid dependence access treatment. We are proud to focus our clinical development experience along with our global regulatory and go-to-market infrastructure to potentially bring arbaclofen placarbil to market as a new choice for the many patients with alcohol use disorder<sup>1,2</sup> and the healthcare professionals who treat them."

Arbaclofen placarbil will be tested for its ability to suppress alcohol cravings, reduce alcohol intake and to possibly facilitate maintenance of abstinence in alcohol dependent people.<sup>5,6</sup> In prior clinical trials, arbaclofen placarbil has demonstrated attributes that may enable convenient dosing, stable plasma exposure and good tolerability.<sup>7</sup>

"We believe that Reckitt Benckiser Pharmaceuticals will be an excellent partner for the further development of arbaclofen placarbil, given their track record of success in the treatment of addiction disorders. XenoPort has completed a substantial amount of preclinical, clinical

pharmacology and manufacturing work and has dosed over 1,300 human subjects with arbaclofen placarbil in various clinical trials," said Ronald W. Barrett, Ph.D., CEO, XenoPort, Inc. "We are very pleased to leverage this work with a partner that now has an exciting opportunity to develop a potential new effective, safe and conveniently dosed medicine that could address an important medical and societal problem."

Under the terms of the agreement, Reckitt Benckiser Pharmaceuticals will receive exclusive rights to develop and commercialize arbaclofen placarbil worldwide for all indications, subject to certain rights by XenoPort to negotiate with Reckitt Benckiser Pharmaceuticals on collaborations for non-addiction indications. In exchange for these rights and upon effectiveness of the agreement, XenoPort is entitled to receive an up-front, non-refundable cash payment of \$20 million and another \$5 million upon the transfer of certain technology and materials to Reckitt Benckiser Pharmaceuticals. XenoPort also will be eligible to receive aggregate cash payments of up to \$70 million upon the achievement by Reckitt Benckiser Pharmaceuticals of certain development and regulatory milestones, as well as up to \$50 million for commercial milestones. In addition, XenoPort is entitled to receive tiered double-digit royalty payments up to the mid-teens on a percentage basis on potential future net sales of arbaclofen placarbil in the United States and high single-digit royalty payments on potential future net sales outside the United States.

The agreement is subject to review by the U.S. Government under the Hart-Scott-Rodino Antitrust Improvements Act, as amended, and will become effective only after clearing review.

### **About Reckitt Benckiser Pharmaceuticals Inc.**

Reckitt Benckiser Pharmaceuticals Inc. is a specialty pharmaceutical company with a decade of heritage in serving the opioid dependence treatment community. Committed to expanding education and access to medical therapies, the company innovates, manufactures and markets medications that, in conjunction with counseling and psychosocial support, treat opioid dependence. Reckitt Benckiser Pharmaceuticals Inc. continues to invest resources in raising awareness of opioid dependence within the community, while also sponsoring training programs for physicians to become certified to treat opioid addicted patients. The company aims to help patients, while also protecting communities from the financial and societal burdens of addiction through mediation-assisted treatment, enabling opioid dependence to be managed within mainstream medical practice. Reckitt Benckiser Pharmaceuticals Inc. is a wholly owned subsidiary of Reckitt Benckiser Group plc, a global company publicly traded on the UK stock exchange.

#### **About XenoPort**

XenoPort, Inc. is a biopharmaceutical company focused on developing and commercializing a portfolio of internally discovered product candidates for the potential treatment of neurological disorders. XenoPort is currently commercializing HORIZANT® (gabapentin enacarbil) Extended-Release Tablets in the United States and developing its novel fumaric acid ester product candidate, XP23829, as a potential treatment for patients with moderate-to-severe chronic plaque type psoriasis and/or relapsing forms of multiple sclerosis. REGNITE® (gabapentin enacarbil) Extended-Release Tablets is being marketed in Japan by Astellas Pharma Inc. XenoPort's pipeline of product candidates also includes a potential treatment for patients with Parkinson's disease.

To learn more about XenoPort, please visit the website at www.XenoPort.com.



# **XenoPort Forward-Looking Statements**

This press release contains "forward-looking" statements, including, without limitation, all statements related to the anticipated effectiveness of XenoPort's license agreement with Reckitt Benckiser Pharmaceuticals; Reckitt Benckiser Pharmaceuticals' future clinical development program for arbaclofen placarbil; the therapeutic and commercial potential of arbaclofen placarbil; and XenoPort's receipt of potential future development, regulatory and commercial milestone payments, as well as potential royalty payments. 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," "could," "intend," "plans," "potential," "will" 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 the ability of the parties to satisfy all the conditions to effectiveness of XenoPort's license agreement with Reckitt Benckiser Pharmaceuticals, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, as amended; the difficulty and uncertainty of pharmaceutical product development and the uncertain results and timing of clinical trials and other studies, including the risk that success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful; the uncertainty of the FDA approval process and other regulatory requirements; the uncertain therapeutic and commercial value of arbaclofen placarbil; XenoPort's dependence on collaborative partners, including the risks that if Reckitt Benckiser Pharmaceuticals were to breach or terminate the license agreement or otherwise fail to successfully develop and commercialize products thereunder and in a timely manner, XenoPort would not obtain the anticipated financial and other benefits of the license agreement and the clinical development or commercialization of arbaclofen placarbil could be delayed or terminated; as well as risks related to future opportunities and plans, including the uncertainty of future operating results. These and other risk factors are discussed under the heading "Risk Factors" in XenoPort's Securities and Exchange Commission filings and reports, including in its Quarterly Report on Form 10-Q for the guarter ended March 31, 2014, filed with the Securities and Exchange Commission on May 9, 2014. 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.

# Reckitt Benckiser Pharmaceuticals IR Contact

Richard Joyce
Director, Investor Relations, RB
Phone: +44 (0) 1753 217800
Email: richard.joyce@rb.com

**Media Contacts** 

Alana Rockland Biosector 2 Phone: 212-845-5651

Francis ADa eldared OD:

Email: <u>ARockland@Biosector2.com</u>

Alice Sofield Biosector 2

Phone: 703-861-5654

Email: ASofield@Biosector2.com

## **XenoPort IR Contact**

Jackie Cossmon
Phone: 408-616-7295
Email: <u>ir@XenoPort.com</u>



#### References

<sup>&</sup>lt;sup>1</sup> World Health Organization Press Release. WHO to meet beverage company representatives to discuss health-related alcohol issues. January 31, 2003. Accessed on May 6, 2014. Available at: http://www.who.int/mediacentre/news/releases/2003/pr6/en/.

<sup>&</sup>lt;sup>2</sup> World Health Organization. Global status report on alcohol and health. 2011. Accessed on May 6, 2014. Available at: http://www.who.int/substance\_abuse/publications/global\_alcohol\_report/msbgsruprofiles.pdf?ua=1.

<sup>&</sup>lt;sup>3</sup> National Institute on Alcohol Abuse and Alcoholism. Alcohol Facts and Statistics. Accessed on May 6, 2014. Available at: <a href="http://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-facts-and-statistics">http://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-facts-and-statistics</a>.

<sup>&</sup>lt;sup>4</sup> The National Center on Addiction and Substance Abuse at Columbia University. Addiction Medicine: Closing the Gap between Science and Practice. June 2012. Accessed on May 6, 2014. Available at: <a href="http://www.casacolumbia.org/addiction-research/reports/addiction-medicine">http://www.casacolumbia.org/addiction-research/reports/addiction-medicine</a>.

<sup>&</sup>lt;sup>5</sup> Heidbreder C. Recent Advances in the Pharmacotherapeutic Management of Drug Dependence and Addiction. Current Psychiatry Reviews, 2005, 1, 45-67.

<sup>&</sup>lt;sup>6</sup> Johnson, B. Update on Neuropharmacological Treatments for Alcoholism: Scientific Basis and Clinical Findings. *Biochem Pharmacol.* 2008 January 1; 75(1): 34–56.

<sup>&</sup>lt;sup>7</sup> Lal et al. The Journal of Pharmacology and Experimental Therapeutics. Arbaclofen Placarbil, a Novel R-Baclofen Prodrug: Improved Absorption, Distribution, Metabolism, and Elimination Properties Compared with R-Baclofen 330:911–921, 2009.