Teva and Xenon Announce Phase II Study of Topical TV-45070 in Patients with Post-Herpetic Neuralgia (PHN) Did Not Meet Primary Endpoint

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JERUSALEM and BURNABY, British Columbia , June 27, 2017 (GLOBE NEWSWIRE) -- Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) (TASE:TEVA) and Xenon Pharmaceuticals Inc. (Nasdaq:XENE) announce top-line results in a Phase II study of topical TV-45070 in patients with post-herpetic neuralgia (PHN). TV-45070 did not meet the primary endpoint of a statistically significant change in pain from baseline to week four as assessed by the numeric rating scale (NRS). Secondary endpoints were also not met. There were no safety concerns in the study.

This was a Phase II proof of concept study seeking to understand the potential for a topical route of Nav1.7 blockade in PHN. Dr. Simon Pimstone, Xenon's President and Chief Executive Officer, said: "While these results are disappointing for us from a scientific perspective and for patients needing new therapies to treat chronic neuropathic pain, Xenon remains focused on advancing its pipeline of neurology-related development candidates, with multiple programs anticipated to enter clinical development in 2017."

The companies plan to further analyze the data from this study to determine the next steps for TV-45070, and may look to present study data at a relevant forthcoming scientific conference.

About TV-45070

TV-45070 is a small-molecule inhibitor of the sodium channel Nav1.7, and other sodium channels, expressed in the pain-sensing peripheral nervous system. TV-45070 was licensed by Xenon to Teva in December 2012.

This Phase II trial was a randomized, double-blind, placebo controlled, parallel group, multicenter study to evaluate the efficacy and safety of TV-45070 in patients with PHN. The study included three treatment groups that received topical ointment containing 4% or 8% TV-45070 or placebo, dosed twice daily. The primary endpoint of this study was the change of average daily pain scores from baseline to week four, measured using an 11-point (0-10) numeric rating scale (NRS).

Secondary endpoints included the percentage of patients with greater than 30% and greater than 50% improvement in pain scores, quality of life measurements and adverse events measurements. The study was carried out at 48 centers in the US and involved 300 patients randomized to 100 patients receiving 4% TV-45070, 100 patients receiving 8% TV-45070 and 100 patients receiving placebo.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) (TASE:TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by approximately 200 million patients in 100 markets every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,800 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has the world-leading innovative treatment for multiple sclerosis as well as late-stage development programs for other disorders of the central nervous system, including movement disorders, migraine, pain and neurodegenerative conditions, as well as a broad portfolio of respiratory products. Teva is leveraging its generics and specialty capabilities in order to seek new ways of addressing unmet patient needs by combining drug development with devices, services and technologies. Teva's net revenues in 2016 were $21.9 billion. For more information, visit www.tevapharm.com.

About Xenon Pharmaceuticals Inc.

Xenon is a clinical stage biopharmaceutical company focused on developing innovative therapeutics to improve the lives of patients with neurological disorders. Building upon our extensive knowledge of human genetics and diseases caused by mutations in ion channels, known as channelopathies, we are advancing – both independently and with our pharmaceutical collaborators – a novel product pipeline of ion channel modulators to address therapeutic areas of high unmet medical need, such as pain and epilepsy. For more information, please visit www.xenon-pharma.com.

Teva Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding TV-45070 which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to:

- *challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals;*
- *our specialty medicines business, including: competition for our specialty products, especially Copaxone®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; our ability to achieve expected results from investments in our product pipeline; competition from companies with greater resources and capabilities; and the effectiveness of our patents and other measures to protect our intellectual property rights;*
- *our business and operations in general, including: our ability to develop and commercialize additional pharmaceutical products; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third party information technology systems or breaches of our data security; the restructuring of our manufacturing network, including potential related labor unrest; the impact of continuing consolidation of our distributors and customers; and variations in patent laws that may adversely affect our ability to manufacture our products;*
- *compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; governmental investigations into sales and marketing practices; potential liability for sales of generic products prior to a final resolution of outstanding patent litigation; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks;*

and other factors discussed in our Annual Report on Form 20-F for the year ended December 31, 2016 ("Annual Report"), including in the section captioned "Risk Factors," and in our other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov and www.tevapharm.com. Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

Xenon's Safe Harbor Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. These forward-looking statements are not based on historical fact, and include statements regarding the anticipated timing of IND submissions with regulatory agencies, the initiation of future clinical trials, the future development plans for TV-45070 and the progress and potential of ongoing development programs. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our or our collaborators' product candidates; our discovery platform or ongoing collaborations may not yield additional product candidates; our efforts to expand our current pipeline may not be successful; any of our or our collaborators' product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones pursuant to our collaboration agreements; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; adverse conditions in the general domestic and global economic markets; as well as the other risks identified in our filings with the Securities and Exchange Commission and the securities commissions in British Columbia, Alberta and Ontario. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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