



Teva and Xenon Announce Enrollment of First Patient in a Phase 2b Study Evaluating TV-45070 for Postherpetic Neuralgia (PHN)

April 2, 2015

JERUSALEM and BURNABY, British Columbia, April 2, 2015 (GLOBE NEWSWIRE) -- Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) (TASE:TEVA) and Xenon Pharmaceuticals Inc. (Nasdaq:XENE) today announced that the first patient has been enrolled into the Phase 2b study designed to evaluate the safety and efficacy of the novel topically applied TV-45070, (4% and 8% w/w Ointment) in patients with Postherpetic Neuralgia (PHN).

TV-45070 is a small molecule inhibitor of the sodium channel Nav1.7 and other sodium channels, including those that are expressed in the pain-sensing peripheral nervous system. It is being developed for the treatment of patients with various pain indications, including neuropathic and osteoarthritis pain.

"Postherpetic neuralgia leaves patients with lasting and very painful sensations that seriously impact the ability to function. It is often highly refractory to existing treatments and there is a significant need for new treatment options," said Dr. Jon Isaacsohn, Teva's Chief Medical Officer. "The field of pain management in general is in need of new options. Teva is making advances with a range of innovative new treatments that will hopefully improve the lives of millions of people suffering from pain caused by debilitating conditions such as PHN and osteoarthritis."

"The initiation of this TV-45070 Phase 2b clinical trial is an important step on the way to fully understanding the potential for Nav1.7 inhibition in relieving patients from the suffering caused by neuropathic pain. This trial, together with the ongoing study in osteoarthritis pain, from which we expect results later this year, should give us a better indication of the value of this novel approach to pain management," said Dr. Simon Pimstone, Xenon's President and Chief Executive Officer.

The Phase 2b clinical study in PHN is a randomized, double-blind, placebo controlled, multi-site study that will evaluate the safety and efficacy of topically applied TV-45070 ointment compared with placebo. Additional information about the trial is available at www.clinicaltrials.gov/ct2/show/NCT02365636.

About Postherpetic Neuralgia (PHN)

PHN is a painful complication of Herpes Zoster or "shingles" in which pain persists for more than 3 months after resolution of the rash. It affects approximately 20% of people who have herpes zoster and increases with age. Elderly patients tend to have more severe and longer lasting PHN. Despite the numerous compounds available for treating PHN, 40% to 50% of PHN patients do not respond to any treatment. The negative impact of PHN on the quality of life can be similar to that caused by life-threatening diseases or serious psychological conditions. PHN can have a significant effect on many aspects of a patient's life, causing chronic fatigue, sleep disorders, difficulty in concentrating, depression and anxiety, anorexia, loss of bodyweight and social isolation.

About TV-45070

TV-45070 (formerly XEN402) is a topically applied small-molecule inhibitor of the sodium channel Nav1.7 and other sodium channels, including those that are expressed in the pain-sensing peripheral nervous system. TV-45070 has potentially broad application in nociceptive pain, mediated by damage or injury to tissues, including the pain sensitivity caused by inflammation, and neuropathic pain mediated by damage, dysfunction or injury of nerves. The pain target Nav1.7 was identified by Xenon using its Extreme Genetics discovery platform. Xenon developed TV-45070 through early clinical development and partnered with Teva through a collaborative development and license agreement established in 2012, providing Teva with an exclusive worldwide license to develop and commercialize TV-45070. Teva is currently conducting a 300-patient, randomized Phase 2b clinical trial of TV-45070 in osteoarthritis of the knee, with data expected in the third quarter of 2015.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) (TASE:TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions to millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,000 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has a world-leading position in innovative treatments for disorders of the central nervous system, including pain, as well as a strong portfolio of respiratory products. Teva integrates its generics and specialty capabilities in its global research and development division to create new ways of addressing unmet patient needs by combining drug development capabilities with devices, services and technologies. Teva's net revenues in 2014 amounted to \$20.3 billion. For more information, visit www.tevapharm.com.

About Xenon Pharmaceuticals Inc.

Xenon is a clinical-stage biopharmaceutical company discovering and developing a pipeline of differentiated therapeutics for orphan indications that it intends to commercialize on its own and for larger market indications that the company intends to partner with global pharmaceutical companies. Xenon has built a core enabling discovery platform, referred to as Extreme Genetics, for the discovery of validated drug targets by studying rare human diseases with extreme traits, including diseases caused by mutations in ion channels, known as channelopathies. Xenon's Extreme Genetics platform has yielded the first approved gene therapy product in the European Union and a broad development pipeline and multiple pharmaceutical partnerships, including with Teva and Genentech. For more information, please visit www.xenon-pharma.com.

Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: the possibility that the transaction with Auspex will not be completed, including due to the failure to obtain the minimum tender condition; uncertainties as to the timing of the transaction; the possibility that the expected benefits of the transaction will not be fully realized by us or may take longer to realize than expected; our ability to develop and commercialize additional pharmaceutical products; competition for our innovative products, especially Copaxone® (including competition from orally-administered alternatives, as well as from potential purported generic equivalents) and our ability to migrate users to our 40 mg/mL version; the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from the research and development efforts invested in our pipeline of specialty and other products; our ability to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2014 and in our other filings with the U.S. Securities and Exchange Commission. 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 statement, whether as a result of new information, future events or otherwise.

Xenon 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 timing of the initiation of and completion of clinical trials, the timing of and results from ongoing clinical trials, the design and enrollment goals for clinical trials and the plans of our collaboration partners and their interactions with regulatory agencies. 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 Extreme Genetics discovery platform may not yield additional product candidates; 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; 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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