Xenon Initiates Phase 2 Clinical Trial of XEN801 to Treat Moderate to Severe Acne

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BURNABY, British Columbia, Feb. 10, 2016 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical-stage biopharmaceutical company, today announced that it has commenced dosing patients in a Phase 2 clinical trial of XEN801, which is a stearoyl Co-A desaturase-1, or SCD1, inhibitor being developed for the treatment of moderate to severe acne.

The Phase 2 clinical trial is a randomized, double-blind, vehicle-controlled, parallel-group study designed to evaluate the efficacy, safety, tolerability and systemic exposure of XEN801 for the treatment of moderate to severe facial acne. Xenon expects to enroll approximately 150 patients with acne at multiple sites, with topline results expected in the fourth quarter of 2016.

Dr. Simon Pimstone, Xenon's President and Chief Executive Officer, commented: “We have met a key corporate milestone as our most advanced proprietary product, XEN801, has now progressed into a Phase 2 trial based on the results from our completed Phase 1 clinical trial. By targeting a reduction in the size and number of sebaceous glands, thereby reducing sebum production, we believe XEN801 is a promising, novel treatment for acne, which we anticipate could be better tolerated and without the serious side effects that often limit the use of currently approved retinoid treatments.”

In the Phase 1 study, XEN801 was found to be safe and generally well tolerated. In total, 48 healthy volunteers were dosed for either a 14-day or 21-day treatment period. A number of different dose volumes of the 1% XEN801 drug product were evaluated in the Phase 1 clinical trial with dosing on the back and face of healthy volunteers to determine the maximum tolerated dose. As expected, the most common side effects were localized, generally mild skin reactions. No serious adverse events were observed. Maximal plasma concentrations of XEN801 were low, whereas the median skin concentration of XEN801 was above the drug concentration predicted for efficacy for all dose volumes evaluated. A Phase 2 dose was selected based on favorable tolerability and skin drug concentrations.

About the XEN801 Phase 2 Clinical Trial
The Phase 2 clinical trial is a randomized, double-blind, multi-center, vehicle-controlled, parallel-group study to determine the safety, tolerability, efficacy and systemic exposure of XEN801 in approximately 150 patients with moderate to severe facial acne. Patients will apply XEN801 (or vehicle placebo) topically to their face for 12-weeks with a 4-week follow up. The primary efficacy endpoint is the percent change in total (inflammatory and non-inflammatory) lesion count from baseline to week 12. Secondary endpoints include the percent change in inflammatory and/or non-inflammatory lesions at different time points throughout the 12 week study as well as a number of Investigator's Global Assessment (IGA) measures.

About Acne
Acne is a multifactorial disease of the pilosebaceous unit, which are skin structures consisting of a hair follicle and its associated sebaceous gland. Increased levels of androgens, such as testosterone, which occurs during puberty, cause an enlargement of the sebaceous gland that increases production of sebum, a naturally occurring oil. Acne develops as a result of blockages in the hair follicles due to the sebaceous glands becoming clogged with excess sebum and dead skin cells. Under these conditions, the bacteria *propionibacterium acnes* can multiply and cause the noticeable inflammatory lesions. Acne prevalence peaks in late adolescence and is estimated to affect 40 to 50 million people in the U.S., of which there are approximately 11 million and 1.2 million individuals with moderate and severe acne, respectively.

About XEN801
XEN801 is a topically administered, selective, small molecule inhibitor of stearoyl Co-A desaturase-1 (SCD1), an enzyme involved in lipid synthesis that is expressed in sebaceous glands in the skin. Xenon believes that XEN801 can have an impact on acne via two distinct mechanisms: firstly, by reducing monounsaturated fatty acids to reduce the production of sebum lipids produced by sebaceous glands, and secondly, by increasing the production of neutrophil gelatinase-associated lipocalin, or NGAL, endogenously which can have an apoptotic (cell death) effect on the cells of the sebaceous glands thereby reducing their size. Xenon has tested this mechanism in human sebocyte cell lines and demonstrated an ability of XEN801 to increase levels of NGAL. Xenon believes these data support a differentiated mechanism of XEN801 compared to other drugs that are approved or are in development for acne.

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.

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 design of a Phase 2 clinical trial of XEN801 and anticipated enrollment, the anticipated timing of topline results in the fourth quarter of 2016, the potential efficacy, future development plans and commercial potential of our product candidates, including XEN801, 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 Extreme Genetics® discovery platform or ongoing collaborations 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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