Xenon Pharmaceuticals Outlines Key Milestones for 2017

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BURNABY, British Columbia, Jan. 08, 2017 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical-stage biopharmaceutical company, today outlined its anticipated key corporate milestones for 2017.

Dr. Simon Pimstone, Xenon's President and Chief Executive Officer, said, “As we enter 2017, these upcoming quarters represent the most data-rich period in our history. We are looking forward to a number of important inflection points for our company: we expect topline data from our XEN801 Phase 2 clinical trial for moderate to severe acne; we anticipate our collaborator, Genentech, will advance its Nav1.7 pain program into Phase 2; and, we look forward to a topline data read-out from the Phase 2b clinical trial of TV-45070 in post-herpetic neuralgia being conducted by our collaborator, Teva. We also expect to advance a novel Nav1.6 inhibitor, which is a potential treatment for epilepsy, into toxicology studies to support an IND filing later this year. Each of these key milestones has the potential to have a meaningful impact on the growth of our company.”

Anticipated Milestones

- XEN801 is a topical stearoyl Co-A desaturase-1, or SCD1 inhibitor, being developed for the treatment of moderate to severe acne. By targeting a reduction in the size and number of sebaceous glands, thereby reducing sebum production, Xenon believes XEN801 is a promising, novel treatment for acne, which could be better tolerated and without the serious side effects that often limit the use of currently approved retinoid treatments.

  Enrollment of 165 subjects is now complete in the XEN801 Phase 2 clinical trial, which is a randomized, double-blind, multi-center, 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. Patients apply a gel formulation of 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 efficacy assessments of inflammatory and/or non-inflammatory lesion counts and Investigator's Global Assessment (IGA) measures. Topline results from the XEN801 Phase 2 clinical trial are expected in the latter part of the first quarter of 2017.

- TV-45070 is a topical sodium channel inhibitor being developed in collaboration with Xenon’s partner, Teva Pharmaceutical Industries Ltd., for the treatment of neuropathic pain. Teva is currently conducting a randomized, double-blind, placebo-controlled Phase 2b clinical trial of TV-45070 in patients with post-herpetic neuralgia, with topline results expected in mid-2017.

- Xenon's collaborator Genentech, a member of the Roche Group, has completed two Phase 1 clinical trials for GDC-0276 and GDC-0310, which are both oral, selective Nav1.7 small-molecule inhibitors. Genentech has indicated that it intends to focus its ongoing development efforts on GDC-0310. Pending a full assessment of the clinical results and ongoing *in vivo* studies, Genentech anticipates initiating a Phase 2 clinical trial in 2017 for the potential treatment of pain.

- Xenon has identified a drug development candidate within its Nav1.6 program, which is focused on developing a potent, selective Nav1.6 inhibitor for the treatment of rare infantile epileptic encephalopathies and other forms of epilepsy. Selective Nav1.6 inhibitors have demonstrated efficacy for seizures in an animal model of Nav1.6 gain-of-function SCN8A epilepsy. In addition, Xenon has generated preclinical data, which support the treatment of adult partial onset epilepsy with potent, selective Nav1.6 inhibitors. Xenon expects to file an investigational new drug (IND) application in the fourth quarter of 2017.

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 our ability to achieve milestones in both our proprietary and partnered development programs, the anticipated timing of the read out of topline results from the Phase 2 clinical trial of XEN801, the anticipated timing of IND submissions with regulatory agencies, the initiation of future clinical trials, the timing of and results from our and our collaborators' ongoing clinical trials and pre-clinical development activities, the plans of our collaboration partners and their interactions with regulatory agencies, the potential efficacy, future development plans and commercial potential of our and our collaborators' product candidates 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; 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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