Elite Pharmaceuticals Reports Topline Results from a Pivotal Fed Bioequivalence Study for SequestOx™

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NORTHVALE, N.J., July 07, 2017 (GLOBE NEWSWIRE) -- Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCBB:ELTP) today reported topline results from a pivotal bioequivalence fed study for SequestOx™. The mean Tmax of SequestOx™ was 4.6 hr with a range of 0.5 hr to 12 hr and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr with a range of 0.5 hr to 12 hr. A key objective for the study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Elite will pause, not proceed with the rest of the clinical trials, and seek clarity from FDA before deciding on the next steps for immediate release SequestOx™. Elite will continue to pursue extended release products with its proprietary abuse deterrent technology

Elite's pipeline objectives for 2017 remain on-target as Elite is planning the submission of one ANDA filing this current quarter and an additional two ANDA filings in the fourth quarter. Elite will update you on the progress of these targets in the next investor call. Elite's ANDA filings already submitted to the FDA combined with the three ANDAs targeted for submission later this year have total U.S. sales, for the branded products and their generic equivalents, of $4 billion according to IMS Health Data. Elite's pipeline will continue to include abuse deterrent products. The next abuse-deterrent product expected to be filed will be a generic version of OxyContin® for which IMS reported approximately $2.5 billion in revenue in 2015.

"We were hoping for better and more decisive results for the reformulated immediate release version of SequestOx™", said Nasrat Hakim, President and CEO of Elite Pharmaceuticals. "We remain positive with respect to Elite's abuse-deterrent and generic pipeline. We will see the results of our hard work over the next six to twelve months."

SequestOx™ is Elite's investigational immediate-release oxycodone with sequestered naltrexone abuse-deterrent opioid product for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate. The study was a pivotal, open-label, randomized, single-dose, three-way, crossover study to evaluate the relative bioavailability and bioequivalence of the modified formulation of SequestOx™ to the original formulation of SequestOx™ and to a comparator product under fed conditions. The study also evaluated the Tmax of a reformulated SequestOx™ compared to the original SequestOx™ formulation and a comparator product under fed conditions.

About Elite's Abuse Deterrent Technology

Elite's proprietary abuse deterrent technology, ART™, is a multi-particulate capsule which contains an opioid agonist in addition to naltrexone, an opioid antagonist used primarily in the management of alcohol dependence and opioid dependence. When this product is taken as intended, the naltrexone is designed to pass through the body unreleased while the opioid agonist releases as intended providing therapeutic pain relief for which it is prescribed. If the multi-particulate beads are crushed or dissolved, the opioid antagonist is designed to release and so block the effects of active opioid agonist. The absorption of the naltrexone is intended to block the euphoria by preferentially binding to the same receptors in the brain as the opioid agonist and thereby reducing the incentive for abuse or misuse by recreational drug abusers. Elite's pharmacological approach to abuse-deterrence can be applied to a wide range of opioids used today in pain management.

About Elite Pharmaceuticals, Inc.

Elite Pharmaceuticals, Inc. is a specialty pharmaceutical company which is developing a pipeline of proprietary pharmacological abuse-deterrent opioid products as well as niche generic products. Elite specializes in oral sustained and controlled release drug products which have high barriers to entry. Elite owns generic and OTC products which have been licensed to TAGI Pharma, Epic Pharma, and Valeant Pharmaceuticals International. Elite currently has eight commercial products being sold, additional approved products pending manufacturing site transfer and the NDA for SequestOx™, for which it just received the CRL from the FDA. Elite's lead pipeline products include abuse-deterrent opioids which utilize the Company's patented proprietary technology and a once-daily opioid. These products include sustained release oral formulations of opioids for the treatment of chronic pain. These formulations are intended to address two major limitations of existing oral opioids: the provision of consistent relief of baseline pain levels and deterrence of potential opioid abuse. Elite also provides contract manufacturing for Ascend Laboratories (a subsidiary of Alkem Laboratories Ltd.). Elite operates a GMP and DEA registered facility for research, development, and manufacturing located in Northvale, NJ. Learn more at www.elitepharma.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Including those related to the effects, if any, on future results, performance or other expectations that may have some correlation to the subject matter of this press release, readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, Elite's ability to obtain FDA approval of the transfers of the ANDAs or the timing of such approval process, delays, uncertainties, inability to obtain necessary ingredients and other factors not under the control of Elite, which may cause actual results, performance or achievements of Elite to be materially different from the results, performance or other expectations that may be implied by these forward-looking statements. These forward-looking statements may include statements regarding the expected timing of approval, if at all, of SequestOx™ by the FDA, the steps Elite may take as a result of the CRL, the results of an End of Review Meeting and what actions the FDA may require of Elite in order to obtain approval of the NDA. These forward-looking statements are not guarantees of future action or performance. These risks and other factors, including, without limitation, Elite's ability to obtain sufficient funding under the LPC Agreement or from other sources, the timing or results of pending and future clinical trials, regulatory reviews and approvals by the Food and Drug

Administration and other regulatory authorities, intellectual property protections and defenses, and the Elite's ability to operate as a going concern, are discussed in Elite's filings with the Securities and Exchange Commission, including its reports on Forms 10-K, 10-Q and 8-K. Elite is under no obligation to update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.