Elite Pharmaceuticals Reports Positive Topline Results from SequestOx™ Pilot Study

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NORTHVALE, N.J., Jan. 30, 2018 (GLOBE NEWSWIRE) -- Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCBB:ELTP) today reported positive topline results from a pilot study conducted for SequestOx™, Elite's immediate release Oxycodone Hydrochloride product that incorporates its proprietary abuse-deterrent technology. An objective of the study was to assess whether the reformulated SequestOx could achieve a Tmax (the mean or median time to the maximum drug concentration in subjects) comparable to the reference drug, Roxicodone, when dosed with the standard high fat meal specified by the FDA. As opposed to the earlier formulation, based on these pilot results, the modified SequestOx™ is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. Elite intends to review with the FDA the study results and discuss the pharmacokinetic study requirements for a re-submission of the NDA.

IMS reports approximately $400 million annually in revenue for the immediate release oxycodone generic market. There is currently one other approved, but not yet commercialized, abuse-deterrent product and many non-abuse deterrent generic products in this market. Immediate release oxycodone is one of the most highly abused opioids in the U.S.

SequestOx is Elite's investigational abuse-deterrent immediate-release oxycodone product with sequestered naltrexone for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate. The study was a Phase 1 pilot, randomized, single-dose, single period, pharmacokinetic study in healthy male and female volunteers in the fed state. The test products included two formulation modifications of SequestOx, a unique abuse-deterrent formulation without sequestered naltrexone, and a reference product. The following table summarizes the Tmax results for the pilot study.

Parameter	Treatment	N*	median	min	max
Tmax	Reference	12	2.25	1.28	5.00
	Test-A	12	2.50	1.25	5.00
	Test-B	11	3.00	1.00	4.00
	Test-C	11	2.50	0.50	3.00

* N=number of subjects

"The reformulated SequestOx™ performed well in this pilot study and should provide a path forward for overcoming prior Tmax issues under fed conditions," commented Nasrat Hakim, President and CEO of Elite Pharmaceuticals. "I'm excited about these outstanding results and look forward to reviewing them with the FDA."

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, Dr. Reddy's Laboratories and Valeant Pharmaceuticals International. Elite currently has nine commercial products being sold, four products filed with the FDA, additional approved products pending manufacturing site transfer and the NDA filing for SequestOx™. 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, and the actions the FDA 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 and intellectual property protections and defenses, 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.

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