# Elite Pharmaceuticals Reports Positive Topline Results from a Pivotal Bioequivalence Study

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NORTHVALE, N.J., Oct. 23, 2018 (GLOBE NEWSWIRE) -- Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCBB: ELTP), a specialty pharmaceutical company developing abuse-deterrent opioids and niche generic products, today reported positive topline results from pivotal bioequivalence studies conducted for an undisclosed immediate-release antibiotic generic product which Elite co-developed with SunGen Pharma. The topline results demonstrated that the generic product was bioequivalent to the branded product in both fasted and fed studies.

This is the second antibiotic product which Elite has developed in collaboration with SunGen Pharma. We reported successful pivotal bioequivalence with the first antibiotic product in August 2018 and now confirm success with a second antibiotic product.

Additionally, the FDA recently completed a preapproval inspection for the first two products, both central nervous system stimulants, co-developed with SunGen and filed with the US Food and Drug Administration ("FDA"). No Form 483 observations were received from this inspection. Further, this is the third consecutive FDA inspection of Elite's facility without a Form 483 observation.

IQVIA (formerly QuintilesIMS Health Data) reported annual revenue of approximately $70 million for the brand and generic market for this product.

The studies were an open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single oral dose, bioequivalence study in healthy adult, human volunteers in both the fed and fasted states.

"The SunGen and Elite collaboration has developed four products which have successfully passed bioequivalence studies," said Nasrat Hakim, Chairman and CEO of Elite. "Two of these products have been filed with the FDA and the two additional products will be filed shortly."

**About SunGen Pharma LLC**
SunGen Pharma, LLC is a privately held specialty pharmaceutical company which develops, contract manufactures, and sells pharmaceutical finished products. SunGen specializes in the development of oral solid extended release and complex injectable products. SunGen has business partnerships with many US based generic pharmaceutical companies to develop, manufacture, and sell several pharmaceutical products in the US.

**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 products which have been licensed to TAGI Pharma, Epic Pharma, and Glenmark Pharmaceuticals, Inc., USA. Elite currently has eleven approved generic products, five generic products filed with the FDA, two approved generic products pending manufacturing site transfer and an NDA filed for SequestOx™. Elite's 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 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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