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

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NORTHVALE, N.J., Aug. 14, 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 being co-developed with SunGen Pharma. The topline results indicate that the generic product is bioequivalent to the branded product in both fasted and fed studies.

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.

IQVIA (formerly QuintilesIMS Health Data) reported annual revenue for the year ending June 2018 were $110 million for the brand and generic market for this product.

"I am pleased we have achieved this milestone and are expected to file this ANDA by year-end. A filing on this product would be our third ANDA filed from our collaboration with SunGen," said Nasrat Hakim, Chairman and CEO of Elite. "Elite continues to build a strong pipeline by combining its own products with those co-developed with SunGen."

"The collaboration between SunGen and Elite has been very productive and the companies continue working on additional products for future filings," said Dr. Jim Huang, Co-CEO of SunGen.

**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, Dr. Reddy's Laboratories, and Glenmark Pharmaceuticals, Inc., USA. Elite currently has eight commercial products being sold, two additional approved products pending launch, four products filed with the FDA, additional approved products pending manufacturing site transfer and the NDA filing 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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