

Elite Pharmaceuticals Reports Positive Topline Results from a Pivotal Bioequivalence Study

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NORTHVALE, N.J., May 30, 2017 (GLOBE NEWSWIRE) -- Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCBB:ELTP) today reported positive topline results from pivotal bioequivalence studies conducted in April of this year for an undisclosed generic product in co-development 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 single dose crossover comparative bioavailability studies in healthy male and female volunteers in both the fed and fasted states. IMS reported approximately \$600 million in revenue for the generic market for this product in 2016.

"We are very pleased to announce this successful BE study for the first of four products under development in collaboration with our partner, SunGen," said Nasrat Hakim, Chairman and CEO of Elite. "According to IMS Health Data, the four brand products and their generic equivalents had total U.S. sales of more than \$3 billion for the twelve months ending June 30, 2016."

"We are thrilled to have positive BE results for the first of the four products under co-development with Elite," said Dr. Jim Huang, Co-CEO of SunGen. "We are very pleased with the collaboration between our two companies and the progress we have made so far with these very important products."

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 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 under review pending approval by the FDA, additional approved products pending manufacturing site transfer and the NDA for SequestOx™, for which it 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.

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