

Elite Pharmaceuticals and SunGen Pharma File ANDA for an Antibiotic

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NORTHVALE, N.J., Jan. 03, 2019 (GLOBE NEWSWIRE) -- Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCBB: ELTP) a specialty pharmaceutical company developing abuse-deterrent opioids and niche generic products, today announced that it filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for a generic version of an antibiotic product. This is the third ANDA that Elite co-developed and filed with SunGen Pharma, LLC ("SunGen"). According to QVIA (formerly QuintilesIMS Health) data the branded product for this antibiotic and its equivalents had total annual U.S. sales of approximately \$94 million for the twelve months ending September 30, 2018.

The product is jointly owned by Elite and SunGen. Elite will manufacture and package the product on a cost-plus basis.

"This is the third ANDA developed and filed with our partner, SunGen. Our first ANDA with SunGen, a generic version of Adderall[®], was approved this December and we look forward to additional approvals and filings in the future," said Nasrat Hakim, President and CEO of Elite. "In addition to our SequestOx[™] NDA filing, Elite has a total of four ANDAs under FDA review."

"We are pleased to have another ANDA filed with the FDA through our partnership with Elite as we work on the launch of the recently approved generic Adderall[®]," 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 U.S.

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 and Glenmark Pharmaceuticals, Inc., USA. Elite currently has twelve approved generic products, three 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, N.J. 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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