Elite Pharmaceuticals Receives FDA Approval for Generic Methadone Hydrochloride Tablets

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NORTHVALE, N.J., Aug. 06, 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 announced that it received approval from the U.S. Food and Drug Administration (FDA) for the Company's abbreviated new drug application (ANDA) for methadone hydrochloride 5 mg and 10 mg tablets. Methadone is indicated for the management of pain severe enough to require daily, around-the-clock long-term opioid treatment and for which alternative treatment options are inadequate. Methadone can also be used for maintenance treatment of opioid addiction (heroin or other morphine-like drugs) in conjunction with appropriate social and medical services.

Glenmark Pharmaceuticals, Inc., Elite's marketing alliance partner, will sell and distribute methadone for Elite for which Elite will receive manufacturing and license fees. Based on QuintilesIMS Health data, the annual retail sales for the brand and generic products were approximately $30 million.

"I am pleased to receive FDA approval for our methadone ANDA filing. We expect methadone to be a key product for our marketing alliance with Glenmark Pharmaceuticals," stated Nasrat Hakim, President and CEO of Elite. "This is our second product approval in the last 30 days. We have four additional ANDAs and an NDA for SequestOx™ currently filed 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 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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