Elite Announces New Development and License Agreement with SunGen Pharma LLC

Release: 7/12/2017 8:32:00 AM

NORTHVALE, N.J., July 12, 2017 (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 it has entered into a new Development and License Agreement (the "Agreement") with SunGen Pharma, LLC ("SunGen") to collaborate, develop and commercialize generic pharmaceutical products based upon a unique drug delivery platform used for extended release products. The parties intend to begin with the development of five generic extended release products and to develop additional such products after that. More than a dozen products utilize this type of technology. This new co-development agreement will build upon the success of the first development agreement signed by Elite and SunGen in 2016.

Under the terms of the Agreement, Elite and SunGen will share the responsibilities and costs of the development and marketing of the products. Upon FDA approval, the products will be owned jointly by Elite and SunGen. Elite will manufacture and package all the products on a cost plus basis.

The product classes include CNS stimulants, anticonvulsives, antipsychotics and antihypertensives. For the twelve months ending March 31, 2017, the five products and their generic equivalents had total U.S. sales of more than $2.5 billion according to IMS Health Data.

"We have been very pleased with the progress and success to-date with our SunGen collaboration and are excited to extend the collaboration to these products," said Nasrat Hakim, Chairman and CEO of Elite.

"Our strategic partnership with Elite is working exceedingly well, and we are pleased to broaden the range of products on which we are collaborating," 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 and OTC products which have been licensed to TAGI Pharma, Epic Pharma, and Valeant Pharmaceuticals International. Elite currently has eight commercial products being sold, additional approved products pending manufacturing site transfer and the NDA for SequestOx™, for which it just 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.

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, the steps Elite may take as a result of the CRL, the results of an End of Review Meeting and what actions the FDA may 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, intellectual property protections and defenses, and the Elite's ability to operate as a going concern, 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.