Elite Pharmaceuticals, Inc.: Elite Pharmaceuticals and SunGen Pharma Receive FDA Approval for Generic Adderall XR(R)

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NORTHVALE, NJ / ACCESSWIRE / December 12, 2019 / Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCQB:ELTP), a specialty pharmaceutical company developing its own generic products, partnered generic products and proprietary abuse-deterrent opioids, today announced that it received approval from the US Food and Drug Administration (FDA) for a generic version of Adderall XR®, an extended-release mixed salt of a single entity Amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate) with strengths of 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg capsules. The product is a central nervous system stimulant and is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). According to IQVIA (formerly QuintilesIMS Health) data, the branded product and its equivalents had total U.S. sales of $1.3 billion for the twelve months ending October 2019.

Generic Adderall XR is jointly owned and the second product approval for our Elite and SunGen Pharma LLC ("SunGen") collaboration. Elite will manufacture and package the product on a cost-plus basis. Lannett Company, Inc. will be the exclusive U.S. distributor.

"We are pleased to have received approval of this second product co-developed with our partner, SunGen," said Nasrat Hakim, President and CEO of Elite. "Launch of this product is our top priority."

"We are very pleased to have another ANDA approval through our partnership with Elite and achieve a significant milestone for Sungen as we work on the launch of the recently approved generic Adderall XR®," said Dr. Jim Huang, Co-CEO of SunGen.

About Lannett Company, Inc.

Lannett Company, founded in 1942, develops, manufactures, packages, markets and distributes generic pharmaceutical products for a wide range of medical indications. For more information, visit the company's website at www.lannett.com.

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, Glenmark Pharmaceuticals, Inc., USA., and Lannett Company, Inc. Elite currently has eleven approved generic products, three generic products filed with the FDA, one 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 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. The information found on Elite's website is not incorporated by reference into this press release and is included for reference purposes only.

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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