

Elite Pharmaceuticals Announces Commercial Launch of Dantrolene Capsules with Marketing Partner Lannett Company

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NORTHVALE, NJ / ACCESSWIRE / June 28, 2019 / Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCQB: ELTP) announced today that marketing partner Lannett Company, Inc. ("Lannett"), has commenced product launch of Elite's generic Dantrolene Capsules.

Elite entered into a license, supply, and distribution agreement ("Agreement") with Lannett for Elite's Abbreviated New Drug Application (ANDA) for Dantrolene Sodium capsules, 25 mg, 50 mg and 100 mg. Elite's product is a generic version of Par Pharmaceutical's (an Endo International Company) Dantrium[®] (Dantrolene Sodium) which is indicated for controlling the manifestations of clinical spasticity.

Lannett will be the exclusive U.S. distributor for Dantrolene Sodium capsules for which Elite will receive manufacturing fees and a profit split. According to IQVIA, Dantrium[®] and its equivalents had total U.S. sales of \$6.4 million for the twelve months ending April 2019.

The U.S. Food and Drug Administration (FDA) granted approval for the transfer of the manufacturing process for the product to the Company's Northvale facility.

"We are pleased to add Dantrolene to our commercial product portfolio and to have Lannett as our marketing partner," said Nasrat Hakim, President and CEO of Elite.

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 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 twelve approved generic products, four 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 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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