

Elite Pharmaceuticals Announces FDA Approval of Phendimetrazine Tartrate Tablets USP

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NORTHVALE, N.J., Jan. 02, 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 has received approval of the Company's abbreviated new drug application (ANDA) from the U.S. Food and Drug Administration (FDA) for Phendimetrazine Tartrate Tablets USP, 35 mg.

Based on recent QuintilesIMS Health data from March 2017, the retail sales for this product is approximately \$4.5 million with three generic competitors. These sales numbers do not include most institutional sales or sales to clinics.

The Phendimetrazine Tartrate approval is from an Elite ANDA filed approximately six years ago. Since the filing, Elite obtained a second, approved Phendimetrazine Tartrate ANDA through Mikah Pharma. Elite has been selling this generic product for more than five years. Elite is considering strategic options, including divestiture, for this newly approved ANDA.

"An ANDA approval for Phendimetrazine Tartrate at the end of 2017 was a welcome occurrence," commented Nasrat Hakim, President and CEO of Elite. "We look forward to additional approvals in 2018 from more recent filings."

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, Dr. Reddy's Laboratories and Valeant Pharmaceuticals International. Elite currently has nine commercial products being sold, four products under review pending approval by the FDA, additional approved products pending manufacturing site transfer and the NDA filing for SequestOx™. 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, 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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