

Eton Pharmaceuticals Submits New Drug Application for DS-200 FDA Previously Granted DS-200 Fast Track Designation

DEER PARK, Ill., March 14, 2019 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc. (Nasdaq: ETON), today announced that the Company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for DS-200 via the Rolling Review process. DS-200 was previously granted Fast Track Designation by the FDA. This important designation is intended to speed the availability of drugs that treat serious conditions and demonstrate the potential to address an unmet medical need.

"The commencement of the NDA submission process for DS-200 marks an important milestone for Eton as we continue to progress DS-200 and our broader late stage pipeline with a new total of four products applications submitted to the FDA," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "Our recent regulatory progress with DS-200 and our growing portfolio of programs is bringing Eton one step closer to making these important medicines available to patients in need. We look forward to working closely with the FDA during the review process while simultaneously planning for a potential commercial launch."

DS-200 is an injectable hospital-use product candidate. Its active ingredient is currently being supplied in the U.S market through an unapproved drug product. For a variety of historical reasons, some drugs, mostly older products, continue to be marketed in the United States in this manner. FDA guidance clearly articulates FDA's expectation that manufacturers of products requiring FDA approval demonstrate that their products are safe and effective. If the DS-200 NDA is approved, Eton expects the current unapproved product to exit the market, consistent with FDA guidelines.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Eton is primarily focused on liquid dosage forms including injectables, oral liquids and ophthalmics. Eton has a diversified pipeline of high-value product candidates in various stages of development and therapeutic areas, including multiple product candidates currently under review by the FDA.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding Eton's business strategy, Eton's plans to develop and commercialize its product candidates, the potential benefits of Eton's product candidates, the expected impact of an approval of an NDA for DS-200, Eton's plans and expected timing with respect to regulatory filings and approvals, and the potential value of Eton's product candidates. These forward-looking statements are based upon Eton's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of developing, obtaining regulatory for and commercializing drugs that are safe and effective for use as human therapeutics, potential delays in regulatory filings and approvals, the risk that the FDA may not approve Eton's NDA for DS-200 and competition from existing products or new products that may be introduced by others. These and other risks concerning Eton's development programs and financial position are described in additional detail in Eton's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Eton undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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