Eton Pharmaceuticals Provides Update on EM-100 Program

DEER PARK, III., July 12, 2019 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that the U.S Food and Drug Administration (FDA) provided Eton's partner with a Complete Response Letter relating to the application for EM-100. No concerns were raised about the clinical data in the application, so it is not anticipated that any additional clinical work will be required. A response to this letter is expected shortly, and the Company remains confident in the approvability of the product.

"We believe the issues cited in the CRL can be addressed in the coming months, and we remain confident that EM-100 will be available to patients as quickly as possible," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals.

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 pending regulatory approval with 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, including statements associated with the expected ability of Eton and its partner to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding the expected impact of the FDA's Complete Response Letter, the timing of a response to such letter, the ability to resolve the issues raised by the letter and the timing of such resolution, the approvability of the product in light if this letter and the timing of such approval and launch. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. 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 forwardlooking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Eton's business, development programs, and financial condition 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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