

Eton Pharmaceuticals Announces Positive Results from Clinical Study Report of ET-104

ET-104 Successfully Demonstrated Bioequivalence to Currently Approved Oral Solid Formulation New Drug Application (NDA) Submission Expected in Fourth Quarter of 2019

DEER PARK, Ill.--(BUSINESS WIRE)--Aug. 19, 2019-- Eton Pharmaceuticals, Inc. (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products today announced positive results from bioequivalence studies of ET-104, Eton's proprietary oral liquid formulation of a molecule frequently used to treat a severe neurological condition.

In bioequivalence studies conducted in 35 human subjects under both fed and fasting conditions, ET-104 demonstrated pharmacokinetic equivalence to a currently FDA-approved oral solid product of the same active ingredient. The 90% confidence intervals for ET-104's area-under-the-curve and peak concentration measurements were within the 80 to 125 percent-range that is commonly used to define bioequivalence. Based on these successful trial results, Eton anticipates submitting an NDA with the U.S Food and Drug Administration (FDA) for the product in the fourth quarter of 2019.

"We are pleased to report positive results for ET-104, which we believe has the potential to meet a significant unmet need for patients," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "We expect to submit the NDA for ET-104 later this year, further growing our near-approval pipeline and strengthening our neurology liquid franchise."

ET-104 is an innovative patent-pending oral liquid formulation of a molecule frequently used to treat a severe neurological condition. ET-104's active ingredient is currently FDA-approved in oral solid form but not as a liquid. ET-104 was developed to address the significant unmet need for patients that require precision dosing or have difficulty swallowing tablets. In oral solid form, ET-104's active ingredient sells over 200 million tablets and capsules annually.

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 two products currently filed 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 to undertake certain activities and accomplish certain goals and objectives. 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 safety and efficacy of Eton's product candidates, Eton's plans and expected timing with respect to regulatory filings and approvals, and the size and growth potential of the markets for Eton's product candidates. 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 forward-looking 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 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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Source: Eton Pharmaceuticals, Inc.

Company:

David Krempa
dkrempa@etonpharma.com
847-805-1077

Investors:
Julie Seidel
Stern Investor Relations, Inc.
Julie.Seidel@sternir.com
212-362-1200

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