

Eton Pharmaceuticals Announces Licensing of Oral Liquid Product Candidate ET-104 New Drug Application expected to be filed in 2019

DEER PARK, Ill., Jan. 24, 2019 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc. (NASDAQ: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that it has entered into a licensing and supply agreement for ET-104, an innovative oral liquid product candidate for the treatment of a neurological condition.

ET-104's active ingredient is approved and marketed in an oral solid formulation, but the active ingredient is not approved by the U.S. Food and Drug Administration (FDA) in liquid form. Presently, patients requiring liquid formulations of the active ingredient are reliant on compounded products. ET-104 is expected to address this significant unmet patient need and will be Eton's third neurology-focused product in its pipeline. Eton's partner plans to file a patent on its unique formula in the first quarter of 2019.

Eton and its partner, Liqmeds Worldwide Limited, a United Kingdom-based pharmaceutical development and manufacturing company, expect to complete a bioequivalence trial in the second half of 2019 and, if successful, expect to file a New Drug Application with the FDA by the end of 2019.

"With over 100 million pills prescribed annually for ET-104's active ingredient, we believe there is a significant opportunity to bring a liquid formulation to patients who are unable to swallow pills," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "We are eager to add ET-104 to our growing pipeline and we expect to continue to actively pursue additional opportunities to add late-stage assets to our portfolio."

Under the terms of the agreement, Eton will be responsible for the regulatory activities and marketing of ET-104 in the U.S. Liqmeds will receive a minority profit share from the product's commercial sales, an upfront payment of \$350,000 and up to an additional \$2.15 million if certain regulatory and commercial milestones are triggered.

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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