Eton Pharmaceuticals Enters Into License Agreement for Two Branded Hospital Product Candidates

Transaction adds an additional potential 2019 product launch to Eton's pipeline
ET-202 NDA was submitted in December 2018; PDUFA date expected to be in Q4 2019
ET-203 NDA expected to be submitted by Q3 2019

DEER PARK, Ill., Feb. 11, 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 an exclusive licensing and supply agreement with Sintetica SA, a Swiss-based pharmaceutical company, to obtain U.S. marketing rights to two injectable product candidates. With the addition of these product candidates, Eton now has three product candidates submitted with the FDA and expects to submit two additional NDAs by the third quarter of 2019.

The licensed product candidates provide Eton with two high-volume, near-term product launch opportunities. The NDA for ET-202 was submitted to the FDA in December 2018 and Eton expects to receive a fourth quarter 2019 Prescription Drug User Fee Act (PDUFA) date. The NDA for ET-203 is expected to be submitted by the third quarter of 2019.

Both products are innovative ready-to-use formulas of existing injectable products that Eton believes to be two of the highest volume compounded products in the hospital setting. The existing FDA-approved products are only available in concentrated versions that must be diluted prior to administration to patients. Hospitals currently purchase non-FDA approved ready-to-use products from compounding facilities, or manually dilute the products in-house. The newly-licensed product candidates have been developed in ready-to-use strengths that can be immediately administered in patients, eliminating the need for additional dilution steps. Eton believes that if approved, ET-202 and ET-203 will offer significant benefits to hospitals over the current compounded products, including:

- Longer shelf-life
- Elimination of compounding errors due to incorrect drug or concentration
- Significantly higher level of sterility assurance
- More consistent supply
- FDA reviewed for safety and efficacy
- Time and cost savings compared to in-house compounding
- Elimination of regulatory risk associated with in-house compounding

Eton estimates the combined addressable market for the products to be in excess of 10 million units annually. The company believes that, if approved, the compelling potential benefits of these ready-to-use products would enable it to take a significant share of the market.

"We are very excited to partner with Sintetica and add an additional 2019 product launch opportunity to our pipeline," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "These potentially high volume hospital product candidates are an ideal strategic fit with Eton's ongoing mission to bring safe, approved pharmaceutical products to markets that are currently reliant on compounded and unapproved products. We plan to immediately begin launch preparation activities in order to facilitate successful commercialization of these important products if approved."

"Sintetica, a recognized leader in innovative formulations, is very pleased to have entered into a partnership with Eton Pharmaceuticals. The combination of high quality manufacturing and dynamic product development at Sintetica, and Eton's energy and experience in the American market make this great for all stakeholders," said Pasquale Mitidieri, Director of the Global Division of Sintetica S.A.

Under terms of the agreement, Sintetica will supply product to Eton at its direct costs and profit from Eton's commercial sales will be shared equally by both parties. Eton will pay Sintetica $3 million upon execution of the agreements and will be obligated to pay an additional $750,000 upon approval of each product.

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 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 potential benefits of Eton's 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, potential delays in regulatory filings and approvals, the risk that the FDA may not approve Eton's product candidates for marketing, the fact that Eton's license agreement with Sintetica may be subject to early termination, 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.

Company Contact:
David Krempa
dkrempa@etonpharma.com
847-805-1077

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

Source: Eton Pharmaceuticals