EyePoint Pharmaceuticals Receives FDA Approval of YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg

October 15, 2018

- The first long-lasting, FDA approved micro-insert for up to three years of continuous control in chronic, non-infectious posterior segment uveitis, the third leading cause of blindness in the U.S.
- Company to host conference call today at 8:30 a.m. ET

WATERTOWN, Mass., Oct. 15, 2018 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ:EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, announced today that the U. S. Food and Drug Administration (FDA) has approved YUTIQ™ (fluocinolone acetonide intravitreal implant) for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. YUTIQ utilizes the Company's Durasert™ drug delivery technology and is a non-bioerodible intravitreal micro-insert in a drug delivery system containing 0.18 mg fluocinolone acetonide, designed to release consistently over 36 months. YUTIQ is supplied in a sterile single-dose preloaded applicator that can be administered in the physician's office. In clinical trials, YUTIQ significantly reduced the rate of recurrent uveitis flares versus sham, and the most common adverse reactions reported were cataract development and increase in intraocular pressure (IOP).

"The approval of YUTIQ by the FDA is a significant milestone achieved by the Company and marks the second approved ophthalmic product in our pipeline that we plan to commercialize ourselves in the U.S.," said Nancy Lurker, EyePoint's President and Chief Executive Officer. "YUTIQ was developed internally by our research team and this approval further validates our capabilities to successfully design, develop and gain regulatory approval for an ophthalmology product to address a disease with high unmet need. Chronic non-infectious uveitis affecting the posterior segment of the eye is the third leading cause of blindness in the U.S. We anticipate a product launch in the first quarter of calendar 2019 and look forward to bringing this innovative treatment to patients suffering from this disease."

"The approval of YUTIQ is an advancement in the treatment of non-infectious posterior segment uveitis, as it delivers consistent dosing without the peaks and valleys of current local corticosteroids, the standard of care. The clinical data have demonstrated that YUTIQ has a meaningful effect to lower recurrence rates at six and twelve-months following treatment. I believe the effect on recurrence rates will be highly beneficial to help to prevent secondary complications that can lead to vision loss. The approval of YUTIQ is an important step forward for patients and caregivers," said Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology at Duke University School of Medicine.

The FDA approved YUTIQ based on clinical data from two randomized, sham injection-controlled, double-masked Phase 3 clinical trials with patient follow-up continuing for three years. After six and 12 months, both clinical trials achieved the primary efficacy endpoint of prevention of recurrent uveitis flares. Although the p-value of less than 0.001 was reported in each clinical trial, the Company will be using a p-value of 0.01 which is reflected in YUTIQ's label.

The first Phase 3 clinical trial met its primary efficacy endpoint at six months with statistical significance ($p < 0.01$, intent-to-treat analysis; recurrence of 18.4% for YUTIQ versus 78.6% for control). This trial yielded similar efficacy through 12 months of follow-up ($p < 0.01$, intent-to-treat analysis; recurrence of 27.6% for YUTIQ versus 85.7% for control). YUTIQ was generally well tolerated through 12 months of follow-up with a mean IOP elevation of 1.3 mmHg compared to 0.2 mmHg in the sham. Cataract surgeries were performed in 33.3% of patients receiving YUTIQ compared to 4.8% for sham.

The second Phase 3 clinical trial also met its primary efficacy endpoint of prevention of recurrence of uveitis flares at six months with statistical significance ($p < 0.01$, intent-to-treat analysis; recurrence of 21.8% for YUTIQ versus 53.8% for control). 12-month recurrence occurred in 32.7% of patients receiving YUTIQ and 59.6% of those receiving sham injection ($p<0.01$, intent-to-treat analysis). As observed in the first Phase 3 clinical trial, YUTIQ was well tolerated with a mean IOP elevation of 2.0 mmHg compared to no change in the sham. Cataract surgeries were performed in 18.0% of patients receiving YUTIQ compared to 8.6% for sham.

The 24-month and 36-month patient follow-up from the first Phase 3 clinical trial of YUTIQ is expected to be reported by the end of calendar 2018 and in the first half of calendar 2019, respectively.

EyePoint is also developing a next-generation, shorter-duration treatment for chronic non-infectious uveitis affecting the posterior segment of the eye, based on the Durasert technology. This insert is designed to offer a shorter delivery period, thus providing physicians with flexibility for multiple dosing intervals. The Company plans to file an application for approval of this insert in 2019. In addition, the Company intends to launch DEXYCU™ for the treatment of post-operative inflammation at the end of cataract surgery, in the first half of calendar 2019.

Conference Call Information

EyePoint will host a conference call today, Monday, October 15, 2018, at 8:30 a.m. ET, to discuss the U.S. approval of YUTIQ. To access the conference call, please dial (877) 312-7507 (local) or (631) 813-4828 (international) at least 10 minutes prior to the start time and refer to conference ID 2887269. A live webcast will be available on the Investor Relations section of the corporate website at http://www.eyepointpharma.com. A webcast replay will also be available on the corporate website at the conclusion of the call.

YUTIQ™ Label & Important Safety Information

YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

In controlled clinical trials, the most common adverse reactions reported were cataract development and increase in intraocular pressure.

YUTIQ is contraindicated in patients with known hypersensitivity to any components of this product, and is also contraindicated in patients with active or suspected ocular or periocular infections, including most viral diseases of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.

About Chronic Non-infectious Uveitis Affecting the Posterior Segment of the Eye

Non-infectious posterior segment uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is believed to be a leading cause of blindness globally. It affects people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior segment uveitis is estimated to affect between 55,000 - 120,000 people resulting in approximately 30,000 cases of blindness, making it the third leading cause of blindness in the U.S. Today, patients with posterior uveitis are typically treated with systemic steroids, but over time frequently develop serious side effects that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects including an increased risk of cancer.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals, Inc. (formerly pSivida Corp.) (www.eyepointpharma.com), headquartered in Watertown, MA, is a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products in indications with high unmet medical need to help improve the lives of patients with serious eye disorders. With the approval of YUTIQ™, the Company has developed four of only five FDA-approved sustained-release treatments for back-of-the-eye diseases. In addition, DEXYCU™ was approved by the FDA on February 9, 2018. DEXYCU, administered as a single intraocular dose at the end of ocular surgery for the treatment of postoperative inflammation, is the first and only FDA-approved intraocular product with this indication. DEXYCU employs the Verisome® extended-release drug delivery technology, which encompasses a broad number of related, but distinct drug delivery systems capable of incorporating an extensive range of active agents, including small molecules, proteins and monoclonal antibodies. ILUVIEN® (fluocinolone acetonide intravitreal implant), a micro-insert for diabetic macular edema, licensed to Alimera Sciences, Inc., is currently sold directly in the U.S. and several EU countries. Retisert® (fluocinolone acetonide intravitreal implant), for posterior uveitis, is licensed to and sold by Bausch & Lomb, Inc. YUTIQ three-year treatment of chronic non-infectious uveitis affecting the posterior segment of the eye is approved by the U.S. FDA. The Company's pre-clinical development program is focused on using its core Durasert™ and the Verisome platform technologies to deliver drugs to treat wet age-related macular degeneration, glaucoma, and other diseases. To learn more about the Company, please visit www.eyepointpharma.com and connect on Twitter, LinkedIn, Facebook and Google+.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about our plans to commercialize YUTIQ and DEXYCU, the expected timing of release of the 24-month and 36-month patient follow-up data for YUTIQ and our expectations regarding the timing of a filing of an application for approval of a next-generation, shorter-duration treatment for posterior segment uveitis, are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements include uncertainties with respect to: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce commercial supply of YUTIQ and DEXYCU and commercialize YUTIQ and DEXYCU in the U.S.; our ability to successfully build a commercial infrastructure and enter into and maintain commercial agreements for the launch of DEXYCU and YUTIQ; the development of our next-generation YUTIQ short-acting treatment for uveitis; potential off-label sales of ILUVIEN for non-infectious posterior segment uveitis (“NIPU”); consequences of fluocinolone acetonide side effects; successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema (“DME”) which depends on the ability of Alimera Sciences, Inc. (“Alimera”) to continue as a going concern; Alimera’s ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; Alimera’s ability to obtain marketing approval for ILUVIEN in its licensed territories for NIPU; potential declines in Retisert royalties; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, contract sales organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; effects of the potential exit of the United Kingdom from the European Union; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. You should read and interpret any forward-looking statements in light of these risks. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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Source: EyePoint Pharmaceuticals, Inc.