EyePoint Pharmaceuticals Announces Presentation of Data Highlighting YUTIQ™ for Posterior Segment Uveitis at the 36th Annual Scientific Meeting of the American Society of Retina Specialists

July 25, 2018

YUTIQ ™delivers positive twelve month efficacy vs sham with reduced rates of recurrence and reduced use of rescue therapies in patients with noninfectious posterior segment uveitis

NDA currently under review by FDA; PDUFA action date of November 5, 2018

WATERTOWN, Mass., July 25, 2018 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ:EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today announced the presentation of twelve month efficacy and safety data supporting the Company's YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg three-year micro-insert for noninfectious posterior segment uveitis. The data were presented at the 36th Annual Scientific Meeting of the American Society of Retina Specialists (ASRS) in Vancouver, BC, Canada.

"Data from the Phase 3 program continue to support the potential for YUTIQ™ to serve as an effective and safe therapy in the thousands of patients suffering from noninfectious posterior segment uveitis," said Nancy Lurker, President and Chief Executive Officer. "Our NDA for YUTIQ™ for posterior segment uveitis is currently under review by the FDA, with a PDUFA action date of November 5, 2018. Noninfectious posterior segment uveitis represents the third leading cause of blindness in the U.S., and, if approved, we believe that YUTIQ™ could serve as a much needed treatment option for this area of high unmet need."

Summaries of the ASRS presentations are as follows:

Title: Confirmatory 1-Year Study Results of an Injectable Fluocinolone Acetonide Intravitreal Insert to Treat Noninfectious Posterior Segment Uveitis
Presenter: Glenn J. Jaffe, MD, Robert Machemer Professor of Ophthalmology, Duke Eye Center
Session Title: Inflammatory and Infectious Diseases Symposium

In this three-year prospective, multi-center, randomized, double masked Phase 3 study, 153 subjects with noninfectious posterior segment uveitis (NIPU) with a history (>1 year) of recurrent NIPU were randomized to receive either an injectable fluocinolone acetonide intravitreal insert (FAi) (N=101) or sham injection (N=52). Efficacy and safety of the FAi were evaluated at one year, with a primary endpoint of NIPU recurrence.

Uveitic recurrences affecting the posterior segment or requiring rescue with peri- or intraocular steroids and/or systemic treatment were reported for 32.7% of FAi treated eyes versus 59.6% of sham eyes (p=0.002). Both groups had small improvements in mean visual acuity at one year, and macular edema was resolved in 67.7% versus 57.1% of FAi and sham eyes, respectively, that had edema recorded at baseline. Through one year, 23.8% and 7.7% of FAi and sham subjects, respectively, experienced IOP increases ≥12 mm Hg in the study eye, with one of the FAi study eyes requiring IOP lowering surgery. Cataract surgery was performed on 18.0% and 8.6% of phakic study eyes in the FAi and sham groups, respectively. The results of this study support previous findings that the FAi is effective to both treat and prevent recurrent uveitis, with transient and/or manageable side effects.

Title: Controlling Uveitic Recurrences: Results From a Phase 3 Study of 0.18 mg Fluocinolone Acetonide Insert (FAi) in Noninfectious Posterior Uveitis
Presenter: Quan Nguyen, MD, MSc, Professor of Ophthalmology Byers Eye Institute, Stanford University
Session Title: Inflammatory and Infectious Diseases Symposium

In this prospective, randomized, double-masked Phase 3 study, 129 subjects with a history (>1 year) of recurrent NIPU were randomized to receive either injectable FAi (N=87) or sham (N=42). The role of FAi in decreasing the rate of inflammation recurrence, as well as number of recurrent episodes, was evaluated.

During the first year of the three-year study, the recurrence rate in FAi randomized eyes was significantly lower than in sham eyes (37.9% vs. 97.6%, respectively; p<0.001). A total of 63 recurrences were reported in FAi treated eyes (0.7±1.22/eye) versus 105 recurrences in sham treated eyes (2.5±1.67/eye). Multiple (>1) recurrences were observed in 18.4% of the FAi treated eyes versus 67% of the sham treated eyes.

Title: Injectable Fluocinolone Acetonide Intravitreal Insert Reduces the Need for Adjunctive Treatment in Noninfectious Posterior Segment Uveitis
Presenter: Sunil Srivastava, MD, Staff Physician, Cole Eye Institute, Cleveland Clinic
Session Title: Inflammatory and Infectious Diseases Symposium

In this controlled, prospective, double masked multi-center Phase 3 study, 129 subjects who had experienced at least 2 separate recurrences of NIPU requiring ≥ 3 months of systemic therapy or ≥ 2 intra- or peri-ocular steroid injections and with a > 1-year history of the disease were randomized to treatment in one study eye with FAi (N=87) or sham (N=42) injection.

Analysis of the full intent-to-treat cohort (N=129) at one year indicated that a single intravitreal injection of FAi provided effective anti-inflammatory treatment for one year and significantly reduced the need for adjunctive therapies. 6.9% (6/87) of FAi eyes, versus 61.9% (26/42) of sham eyes received at least one intra/peri-ocular steroid injection. Of the 6 eyes that required intra/peri-ocular steroid injection, Four required only a single injection through 12 months while half of the 26 sham eyes required multiple injections up to maximum of five. Systemic treatment was used in 19.5% and 40.5% of FAi and sham patients, respectively. Topical Ophthalmic steroids were prescribed to 20.7% and 47.6% of FAi and sham eyes, respectively.

About Noninfectious Posterior Segment Uveitis

Noninfectious 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 in the developed and developing countries. 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 affects between 80,000 - 100,000 people. 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. The Company has developed three of only four 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. The New Drug Application (NDA) for EyePoint's lead product candidate, YUTIQ™ three-year treatment of non-infectious uveitis affecting the posterior segment of the eye, has been accepted for filing by the FDA and is currently under standard review with a Prescription Drug User Fee Act (PDUFA) date of November 5, 2018. 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 REFORM 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 or believe may occur in the future 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; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema, which depends on Alimera's ability 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; the number of clinical trials and data required for marketing approval for YUTIQ™ in the U.S.; our ability to use data in promotion for YUTIQ which includes clinical trials outside the U.S.; our ability to successfully commercialize DEXYCU™ in the U.S.; our ability to successfully build a commercial infrastructure and enter into commercial agreements for the launch of DEXYCU and YUTIQ, if approved; our ability to successfully commercialize YUTIQ, if approved, in the U.S.; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; the development of our next-generation Durasert shorter-duration treatment for uveitis; 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, 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 U.K. exit from the EU; 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.

Contact

Investors:

Argot Partners
Kimberly Minarovich
(646) 368-8014
kimberly@argotpartners.com

Joseph Rayne
(617) 340-6075
joseph@argotpartners.com

Media:

Thomas Gibson
(201) 476-0322
tom@tomgibsoncommunications.com

Source: EyePoint Pharmaceuticals, Inc.